Curtin School of Nursing

Faculty of Health Sciences

The Use of Self-Management, Group Education to Reduce Fear of Hypoglycaemia as a Barrier to Physical Activity in Adults Living with Type 1 Diabetes: A Feasibility Study.

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This thesis is presented for the Degree of
Doctor of Philosophy
of
Curtin University

October 2021

Declaration

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

The research presented and reported in this thesis was conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007) – updated 2018. The proposed research study received human research ethics approval from the Curtin University Human Research Ethics Committee (EC00262), Approval Number HRE2018-0795.

Signature: Date: 4th October 2021

Acknowledgements

Acknowledgement of Traditional Owners

I acknowledge the Traditional Custodians of the land on which this research was conducted, the Whadjuk people of Noongar Boodjar. I recognise their continued connection to the land and waters of this beautiful place and acknowledge that they never ceded sovereignty. I pay my respects to Elders past and present.

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Glossary of Terms

For the purposes of this thesis, the following terms are defined (in order of appearance throughout the thesis):

Physical activity
"Any bodily movement produced by skeletal muscles that results in energy expenditure" (Caspersen et al., 1985, p. 126). It can include daily activities such as household chores, occupational activity, leisure time activity and incidental activity.

Exercise
A subcategory of physical activity and is activity that is structured and repetitive, with the goal to improve or maintain fitness (Caspersen et al., 1985).

LADA
Latent autoimmune diabetes of adults (LADA), also commonly referred to as 'type 1.5 diabetes' or 'slow evolving immune-mediated diabetes of adults', is defined as either slow and progressive onset of type 1 diabetes or type 2 diabetes with early or fast destruction of beta cells (Bonora & DeFronzo, 2019; World Health Organisation, 2019).

Hyperglycaemia
Blood glucose levels above 14.9 mmol/L. Exposure to blood glucose levels greater than 14.9 mmol/L are associated with a greater level of impairment during hyperglycaemia (Craig et al., 2011).

Hypoglycaemia
A blood glucose level of less than or equal to 3.9 mmol/L (Seaquist et al., 2013).

Fear of hypoglycaemia
Hypoglycaemia is life-threatening and can lead to serious physical and psychological sequelae and can in turn lead to profound fear of future hypoglycaemic episodes (Vallis et al., 2014). Fear and anxiety related to hypoglycaemia can lead to deleterious behaviours and management

strategies in an attempt to avoid an episode (Martyn-Nemeth et al., 2017).

Fear of hypoglycaemia as a barrier to physical activity	A fear of exercise-induced hypoglycaemia resulting in avoidance of physical activities thought to precipitate it. This may or may not be related to a fear of hypoglycaemia in broader diabetes management.
Meta-inference	"An overall conclusion, explanation, or understanding developed through an integration of the inferences obtained from the qualitative and quantitative strands of a mixed methods study" (Tashakkori & Teddlie, 2008, p. 2).

Abstract

Introduction: Physical activity is an important feature of type 1 diabetes (T1D) management as it improves cardiovascular health, reduces exogenous insulin requirements, and may improve glycaemia. Despite these benefits, rates of physical inactivity are higher in those living with T1D than the general population. In Australia, approximately 65% of adults living with T1D are not meeting current physical activity recommendations. Due to the complex nature of blood glucose management in response to physical activity, people living with T1D experience unique barriers to activity which may not be addressed using physical activity initiatives aimed for the general population.

Aim: The aim of this research was to provide an understanding of the unique barriers and facilitators of physical activity in adults living with T1D (systematic scoping review) and how self-management, group education can be used to address diabetes-specific barriers, specifically fear of hypoglycaemia (mixed methods study).

Methods: A systematic scoping review explored the source and quality of existing evidence investigating barriers to and facilitators of physical activity in adults living with T1D in any environment or care setting. Then, a two-phase, explanatory sequential mixed methods study evaluated the feasibility, including acceptability and preliminary efficacy of a pre-existing self-management group education program designed to reduce fear of hypoglycaemia as a barrier to physical activity in adults living with T1D. The first phase was a single-blinded, pilot randomised controlled trial of adults aged between 18 and 65 years, living with T1D in regional and metropolitan Perth, Western Australia. Participants were randomised to standard care (control) or intervention (a pre-existing program, Type 1 TACTICS for Exercise©). The intervention was a self-management group education program which consisted of an initial 3-hour session, a 1-hour follow-up booster session (4-weeks after the initial), and an ongoing private Facebook™ group. The intervention was facilitated using behaviours consistent with Social Cognitive Theory and Dual Process Theory. The control was two, 1-hour didactic PowerPoint sessions covering general physical activity recommendations, 4-weeks apart and aimed to mimic standard care. Primary outcomes of this study were feasibility and acceptability of the study procedures and change to barriers to physical activity and fear of hypoglycaemia. Secondary outcomes were change to attitudes and intentions toward physical activity, self-reported participation in physical activity, self-efficacy, diabetes distress, and well-being. Bayesian comparison was used to calculate effect sizes (Cohen's d) of the between-group difference scores. The second phase of the mixed methods study used focus group

interviews to explore and attempt to explain the quantitative findings. Participants for this phase were recruited from those who did not withdraw from phase one and remained blinded to their study arm until the conclusion of the interview. Interview recordings were transcribed verbatim and analysed using a 4-stage inductive content analysis approach. Quantitative and qualitative data integration was achieved at three levels: design, methods, and interpretation and reporting. A visual joint display was used to demonstrate how the scoping review findings informed the mixed methods objectives and how qualitative data *confirmed*, *explained*, and or were *discordant* to quantitative findings.

Results: The systematic scoping review found that the literature examining barriers to and facilitators of physical activity for people living with T1D was limited and was dominated by articles possessing methodological concerns. Hypoglycaemia/fear of hypoglycaemia was the most frequently identified barrier but was rarely explicitly targeted when exploring facilitators of physical activity. Extremely few studies trialled behaviour change interventions targeting physical activity using robust study designs and of those that did, the majority were pilot studies. The pilot randomised controlled trial randomised 117 participants with T1D, 86 (74%) of whom provided baseline data and attended initial workshops. Participants were 45±12 years of age, reported high levels of activity, and had been living with T1D for 20±14 years. Of these participants, 81% attended the booster workshop 4-weeks later. Small-to-moderate effect sizes [ESs] in favour of the intervention were observed at 12 weeks for overall barriers to physical activity (ES, -0.38; highest density interval, [-0.92 to 0.17]), self-efficacy for blood glucose management after physical activity (ES, 0.45; highest density interval, [0 to 0.91]), diabetes distress (ES, -0.29; highest density interval, [-0.77 to 0.15]) and well-being (ES, 0.36; highest density interval, [-0.12 to 0.8]). Pilot trial participants from the control (n=12) and intervention (n=9) arms participated in focus group interviews. Study procedures were widely accepted, however randomisation and aspects of the questionnaire were of concern to a small number of participants. Group education was the accepted and preferred method of education on this topic; there was ambivalence towards the private Facebook™ group. Finally, mixed methods meta-inferences indicated that the intervention and the study methods used to evaluate it were feasible and acceptable to research participants. Data integration confirmed preliminary positive intervention efficacy in favour of the intervention for mental health, fear of hypoglycaemia as a barrier to physical activity, and self-efficacy.

Conclusion: For the first time, T1D-specific barriers and facilitators of physical activity have been systematically reviewed and presented. Type 1 diabetes-specific interventions grounded in behaviour change theory to address inactivity in this population are needed.

Mixed-methods evaluation has shown theory-driven, self-management group education to be acceptable and the preferred method of education in T1D management for physical activity. Data integration has also revealed a single-blinded randomised controlled trial design is feasible to administer and acceptable to participants. Future trials should target a less active sample and offer a more realistic control which better reflects standard care in Australia. A definitive trial is justified to further test the efficacy findings and utility of Type 1 TACTICS for Exercise© for improving physical activity participation.

Publications and Presentations

Journal Publications

Brennan, M. C., Albrecht, M. A., Brown, J. A., Leslie, G. D., & Ntoumanis, N. (2021). Self-management group education to reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes: A pilot randomised controlled trial. *Canadian Journal of Diabetes, S1499-2671(21)00001-0. Advance online publication.*

Brennan, M. C., Brown, J. A., Leslie, G. D., & Ntoumanis, N. (2021). Acceptability of self-management group education to reduce fear of hypoglycemia as a barrier to physical activity in adults with type 1 diabetes: A mixed methods approach. *Canadian Journal of Diabetes. Advance online publication.*

Brennan, M. C., Brown, J. A., Ntoumanis, N., & Leslie, G. D. (2021). Barriers and facilitators of physical activity participation in adults living with type 1 diabetes: A systematic scoping review. *Applied Physiology, Nutrition, and Metabolism, 46*(2), 95-107. **(Editor's choice)**

Brennan, M. C., Leslie, G. D., Ntoumanis, N., & Brown, J. A. (2021). Group self-management education to address fear of hypoglycaemia as a barrier to physical activity: The role of behaviour change theories. *Australian Diabetes Educator, 24*(1).

Brennan, M., Brown, J. A., Ntoumanis, N., & Leslie, G. D. (2020). Barriers and facilitators to physical activity participation in adults living with type 1 diabetes: A scoping review protocol. *JBI Database of Systematic Reviews and Implementation Reports, 18*(0), 1-7.

Conference and Public Presentations (Appendix D)

Brennan, M. C., Albrecht, M. A., Brown, J. A., Leslie, G. D., Ntoumanis, N. (2020, November). *Type 1 TACTICS for Exercise$^{\copyright}$: Reducing fear of hypoglycaemia as a barrier to physical activity* [Online oral presentation]. Australasian Diabetes Congress, Gold Coast, Australia.

Brennan, M. C., Albrecht, M. A., Brown, J. A., Leslie, G. D., Ntoumanis, N. (2020, November). *Type 1 TACTICS for Exercise©: Results of a pilot randomised controlled trial.* [Online oral presentation]. Australasian Diabetes Congress, Gold Coast, Australia.

Brennan, M. C. (2020, October). *Type 1 and physical activity*. Diabetes WA, An Evening for Discussion: Type 1 Diabetes and Physical Activity, Perth, Australia.

Brennan, M. C., Brown, J. A., Leslie, G. D., Ntoumanis, N. (2020, March). *Group education to address fear of hypoglycaemia as a barrier to physical activity in adults living with type 1 diabetes: A progress report.* [Oral presentation]. Australian Diabetes Educator Association, WA Branch conference, Bunbury, Australia.

Brennan, M. C., Brown, J. A., Leslie, G. D., Ntoumanis, N. (2019, October). *Addressing fear of hypoglycaemia as a barrier to physical activity*. JDRF-PEAK/EXTOD Conference, Glasgow, United Kingdom.

Brennan, M. C. (2019, August). *The highs and lows of physical activity.* [Oral presentation]. 3-Minute Thesis Competition, Curtin University, Perth, Australia. **(Finalist)**

Brennan, M. C. (2019, March). *Addressing barriers to physical activity for people living with type 1 diabetes: Is group, self-management education the answer?* [Oral presentation]. Mark Liveris Research Student Seminar, Perth, Australia.

Copyright Statement

Statement of Contribution of Others

This thesis contains published work, all of which has been co-authored. The bibliographical details of the work, a description of the work, and an estimated percentage of contribution (%) of each author are listed below (in order of publication):

Publication 1: Brennan, M. C.,, Brown, J. A., Ntoumanis, N., & Leslie, G. D. Title: (2020). Barriers and facilitators to physical activity participation in adults living with type 1 diabetes: A scoping review protocol. *JBI Database of Systematic Reviews and Implementation Reports, 18*(0), 1-7.

Author contribution	Conception & design	Acquisition of data & method	Data conditioning & manipulation	Analysis & statistical method	Interpretation & discussion	Critical review
Marian Brennan (75%)	X	X		X		
Dr Janie Brown (10%)	X	X		X		X

Co-author 1 acknowledgement:
I acknowledge that these represent my contribution to the above research output and I have approved the final version.

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Co-author 2 acknowledgement:
I acknowledge that these represent my contribution to the above research output and I have approved the final version.

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Co-author 3 acknowledgement:
I acknowledge that these represent my contribution to the above research output and I have approved the final version.

Signed: Date: 4/10/2021

Publication 2: **Brennan, M. C.,** Brown, J. A., Ntoumanis, N., & Leslie, G. D.
Title: (2021). Barriers and facilitators of physical activity participation in adults living with type 1 diabetes: A systematic scoping review. *Applied Physiology, Nutrition & Metabolism, 46*(2), 95-107.

Author contribution	Conception & design	Acquisition of data & method	Data conditioning & manipulation	Analysis & statistical method	Interpretation & discussion	Critical review
Marian Brennan (70%)	X	X	X	X	X	
Dr Janie Brown (20%)	X	X		X	X	X

Co-author 1 acknowledgement:
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Prof. Nikos Ntoumanis (5%)	X			X	X	X

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Prof. Gavin Leslie (5%)	X			X	X	X

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I acknowledge that these represent my contribution to the above research output and I have approved the final version.

Signed: Date: 4/10/2021

Publication 3: Brennan, M. C., Leslie, G. D., Ntoumanis, N., & Brown, J. A.
Title: (2021). Group self-management education to address fear of hypoglycaemia as a barrier to physical activity: The role of behaviour change theories. *Australian Diabetes Educator, 24*(1).

Author contribution	Conception & design	Acquisition of data & method	Data conditioning & manipulation	Analysis & statistical method	Interpretation & discussion	Critical review
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Co-author 1 acknowledgement:
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Signed: Date: 4/10/2021

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I acknowledge that these represent my contribution to the above research output and I have approved the final version.

Signed: Date: 4/10/2021

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I acknowledge that these represent my contribution to the above research output and I have approved the final version.

Signed: Date: 4/10/2021

Publication 4: Brennan, M. C., Albrecht, M. A., Brown, J. A., Leslie, G. D., & Ntoumanis, N.

Title: (2021). Self-management group education to reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes: A pilot randomised controlled trial. *Canadian Journal of Diabetes, S1499-2671(21)00001-0. Advance online publication.*

Author contribution	Conception & design	Acquisition of data & method	Data conditioning & manipulation	Analysis & statistical method	Interpretation & discussion	Critical review
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Signed: Date: 4/10/2021

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Signed: Date: 4/10/2021

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Co-author 4 acknowledgement:
I acknowledge that these represent my contribution to the above research output and I have approved the final version.

Signed: Date: 4/10/2021

Publication 5: Brennan, M. C., Brown, J. A., Leslie, G. D., & Ntoumanis, N.
Title: (2021). Acceptability of self-management group education to reduce fear of hypoglycemia as a barrier to physical activity in adults with type 1 diabetes: A mixed methods approach. *Canadian Journal of Diabetes. Advance online publication.*

Author contribution	Conception & design	Acquisition of data & method	Data conditioning & manipulation	Analysis & statistical method	Interpretation & discussion	Critical review
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Dr Janie Brown (5%)	X	X		X	X	X

Co-author 1 acknowledgement:
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I acknowledge that these represent my contribution to the above research output and I have approved the final version.

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Co-author 3 acknowledgement:
I acknowledge that these represent my contribution to the above research output and I have approved the final version.

Signed: Date: 4/10/2021

Chapter 1   Thesis Introduction

1.1   Introduction

Physical inactivity is recognised as a global public health problem and is considered the fourth leading risk factor for global mortality (Ekelund et al., 2020; Ekelund et al., 2019; Kohl et al., 2012; Stamatakis et al., 2019). People who are insufficiently active have a 20-30% increased risk of premature death compared to those who are sufficiently active (World Health Organisation, 2020b). Regular physical activity participation has been shown to reduce the risk of coronary heart disease, stroke, type 2 diabetes (T2D), hypertension, colon and breast cancer, depression, and can assist weight management (Ekelund et al., 2019; Lee et al., 2012; Stamatakis et al., 2019; World Health Organisation, 2010). The World Health Organisation recommends adults aged between 18-65 years should participate in 150-300 minutes of moderate-intensity or 75-150 minutes of vigorous-intensity physical activity per week, include at least two days of muscle-strength activity, and reduce sedentary time (World Health Organisation, 2020b).

Though often used interchangeably, the terms physical activity and exercise are not synonymous. Physical activity is defined as "any bodily movement produced by skeletal muscles that results in energy expenditure" (Caspersen et al., 1985, p. 126). It can include daily activities such as household chores, occupational activity, leisure time activity and incidental activity. Exercise is a subcategory of physical activity and is activity that is structured and repetitive, with the goal to improve or maintain fitness (Caspersen et al., 1985). The use of these terms hereafter will be consistent with the aforementioned definitions.

Despite the well documented benefits of physical activity, physical inactivity is on the rise in many countries and is influenced by population aging, cultural values, socioeconomic status, gender, rapid unplanned urbanisation, and globalisation (Kohl et al., 2012; World Health Organisation, 2010, 2020b). Insufficient activity has increased from 31.6% to 36.8% in high-income countries between 2001 and 2016 (World Health Organisation, 2020b). In Australia, 1 in 2 adults are not meeting physical activity recommendations; these rates have remained unchanged since 2011 (Australian Institute of Health and Welfare, 2020). In 2018 the World Health Organisation launched the Global Action Plan on Physical Activity 2018-2030 which aims to reduce physical inactivity by 15% by the year 2030 (World Health Organisation, 2018). The goal to increase physical activity across the globe is consistent with the universal right to health and the opportunity to

participate in physical activity should be afforded to all (World Health Organisation, 2018), including those living with chronic health conditions.

Physical activity plays an important role in the management of 26 chronic conditions including psychiatric conditions, neurological conditions, metabolic conditions, cardiovascular conditions, pulmonary conditions, musculo-skeletal disorders, and cancer (Pedersen & Saltin, 2015). However, for many living with chronic conditions, physical activity appears out of reach, leading to poor physical activity uptake in these populations (Janevic et al., 2012; Kwan et al., 2012; Valero-Elizondo et al., 2016). People living with chronic conditions often experience complex and unique barriers to physical activity, in addition to barriers experienced by the general population, which may contribute to these high rates of inactivity (Bullard et al., 2019). Type 1 diabetes (T1D) is one of these complex chronic conditions for which physical activity is essential but extremely difficult to manage.

1.2   Background

1.2.1   Type 1 Diabetes

Type 1 diabetes is an autoimmune condition affecting the insulin producing pancreatic beta cells found in the Islets of Langerhans. It is a multifactorial condition with genetic, metabolic, and environmental predisposing factors which promote a chronic autoimmune response (Bonora & DeFronzo, 2019). Environmental factors are believed to include factors favouring infection and inflammation such as viral infections, diet and gut permeability, and dysregulation of innate immunity (Bonora & DeFronzo, 2019). This autoimmune response rapidly destroys the beta cells, resulting in permanent insulin deficiency for the person living with T1D. Type 1 diabetes is commonly diagnosed in children and adolescents, but can be diagnosed at any age (Maahs et al., 2010). Type 1 diabetes differs from the more commonly diagnosed, T2D in that T2D is characterised by increased blood glucose as a result of insulin resistance and reduced pancreatic insulin secretion, as opposed to acute insulin deficiency (Khawandanah, 2019).

At times, the distinction between T1D and T2D is not straightforward and there is growing evidence to suggest an overlap between the two (Bonora & DeFronzo, 2019; Khawandanah, 2019). Although strongly debated, latent autoimmune diabetes of adults, also commonly referred to as 'type 1.5 diabetes' or 'slow evolving immune-mediated diabetes of adults', is defined as either slow and progressive onset of T1D or T2D with early or fast destruction of beta cells (Bonora & DeFronzo, 2019; World Health

Organisation, 2019). Regardless of the definition, latent autoimmune diabetes of adults results in eventual destruction of beta cells, resulting in complete insulin deficiency and for the purposes of this thesis, latent autoimmune diabetes of adults is included in the classification of T1D.

1.2.1.1 Prevalence

Type 1 diabetes is one of the most prevalent chronic diseases in childhood (International Diabetes Federation, 2019) and its incidence is estimated to be rising by approximately 3% annually (Bonora & DeFronzo, 2019). It accounts for about 10% of all diabetes cases and is most common among people of European descent (Bonora & DeFronzo, 2019). Global prevalence of T1D is difficult to determine, however the International Diabetes Federation reports 132,600 new cases of T1D each year in youth aged between 0-19 years (International Diabetes Federation, 2017). The National Diabetes Services Scheme estimates there are approximately 128,000 people currently living with T1D in Australia. Although commonly diagnosed in the young, most Australians (89%) currently living with the condition are over the age of 20, and 64% are over the age of 40 (Australian Institute of Health Welfare, 2020; National Diabetes Services Scheme, 2021).

1.2.1.2 Complications

Type 1 diabetes is associated with excess mortality worldwide (Miller et al., 2016; Morgan et al., 2015). Total mortality, cardiovascular disease mortality, and hospitalised cardiovascular disease events are significantly higher (fivefold, 20-30-fold, and eightfold, respectively) compared with age-matched populations (Miller et al., 2016). In contrast to older age groups in Australia, people living with T1D under the age of 40 years are not experiencing a decline in diabetes mortality (Harding et al., 2016). Approximately 40% of people currently living in Australia with T1D have one or more diabetes-related complications (Juvenile Diabetes Research Foundation, 2021).

High mortality and hospitalisation associated with T1D are largely a consequence of chronic diabetes macro- and microvascular complications but can also occur following acute glycaemic emergencies (Paneni et al., 2013). Hypoglycaemia (a blood glucose level less than or equal to 3.9mmol/L) is the most common and frequent side-effect of any anti-diabetes therapy (Seaquist et al., 2013; Umpierrez & Korytkowski, 2016). On average, people living with T1D experience two episodes of symptomatic hypoglycaemia per week and between one to three episodes of severe hypoglycaemia (requiring assistance from another person) per year (Cryer, 2016). Recurrent episodes of hypoglycaemia carry short and long-term health implications. Acute symptoms of hypoglycaemia include heart

palpitations, anxiety, sweating, difficulty speaking and confusion, while prolonged episodes can lead to loss of consciousness and seizures (Cryer, 2016). Recurrent, severe hypoglycaemia can lead to a number of long-term complications including impaired hypoglycaemia awareness, cardiac arrhythmias, and neurological sequelae (Cryer, 2016). These acute and chronic consequences of hypoglycaemia may provoke fear of an episode, leading to avoidance of activities known to increase the likelihood of hypoglycaemia, including physical activity (Wild et al., 2007). Fear of hypoglycaemia as a barrier to physical activity participation is the focus of this research.

Acute hyperglycaemia may inflict unpleasant transient symptoms including headache, lethargy, blurred vision, poor concentration and fluctuation in mood. An episode of hyperglycaemia with significant insulin deficiency can result in diabetes ketoacidosis, a potentially life-threatening condition (Umpierrez & Korytkowski, 2016). In this situation an increase in circulating counter-regulatory hormones (catecholamines, cortisol, and growth hormone) increases hepatic glucose production and promotes hyperglycaemia. Production of ketone bodies is subsequently accelerated, while the metabolism and clearance of these bodies is decreased, resulting in metabolic acidosis (Umpierrez & Korytkowski, 2016). Patients typically present for medical attention within hours to days of developing polyuria, polydipsia, and weight loss. In Australia, 40% of diabetes ketoacidosis presentations are precipitated by "poor adherence to treatment" (Umpierrez & Korytkowski, 2016).

In addition to the implications of acute hyperglycaemia, chronic hyperglycaemia results in endothelial and smooth muscle dysfunction facilitating a pro-inflammatory state, leading to atherosclerotic changes (Paneni et al., 2013). These vascular changes are hastened by comorbid hypertension and dyslipidaemia, and genetic predisposition. Left undetected and untreated, vascular complications including cardiovascular disease, cerebrovascular disease, peripheral vascular disease, neuropathy, nephropathy, and retinopathy can ensue. These serious complications have the potential to severely impact the person's daily function and quality of life (Cryer, 2016).

Like many other complex chronic conditions and owing to the demand placed on individuals, T1D can predispose individuals to a range of psychological difficulties (Craig et al., 2011). It is estimated that 20-30% of people living with T1D experience elevated diabetes distress that will affect self-management behaviours and glycaemic management (Sturt et al., 2015). Correlates of severe psychological distress included young age, low education levels, low household income, obesity, current smoking, no leisure-time physical activity, presence of one or more macrovascular complications, and disability. In

Australia, the Diabetes MILES-2 survey revealed moderate-to-severe depressive and anxiety symptoms in 24% and 16% of T1D respondents, respectively (Ventura et al., 2016). Diabetes distress relates to the emotional burdens, worries, and stresses associated with managing and living with diabetes (Fisher et al., 2014) and was experienced by 24% of T1D respondents (Ventura et al., 2016).

1.2.1.3   Management

Daily management of T1D seeks to minimise hyper and hypoglycaemia events, while endeavouring to reduce the risk of long-term diabetes-related complications (Craig et al., 2011). The principal treatment for T1D is lifelong exogenous insulin, delivered by multiple daily injections or continuous subcutaneous insulin infusion. Adjunct management strategies include nutrition (primarily carbohydrate quantification), glucose monitoring, physical activity, and diabetes self-management education. Daily carbohydrate and insulin requirements are routinely affected by confounding factors including activity, hormones, stress, illness, pain and extreme weather. Achieving euglycaemia is complex and requires extensive self-management, experience, knowledge, and skill by the person living with T1D (Craig et al., 2011).

1.2.1.3.1   Insulin

Insulin therapy has evolved tremendously over its 100-year history. Patients can now access recombinant human insulin and advanced insulin analogues which closely mimic endogenous insulin secretion (Hirsch et al., 2020). Rapid-acting insulin analogues are recommended to reduce the risk of hypoglycaemia (American Diabetes Association, 2020). In the landmark Diabetes Control and Complications Trial, intensive insulin treatment was shown to reduce the incidence of macro- and microvascular complications more than 10 years after active treatment (The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Study Research Group, 2016). People living with T1D are routinely treated with either multiple daily injections consisting of prandial and basal insulin, or continuous subcutaneous insulin infusion. A systematic review and meta-analysis found that the use of continuous subcutaneous insulin infusion had modest advantages for lowing glycated haemoglobin (HbA1c) (-0.3% [95% CI -0.58—0.02]) and reducing episodes of severe hypoglycaemia, though the choice of therapy remains with the individual living with T1D (Yeh et al., 2012).

1.2.1.3.2   Nutrition

Nutritional management plays an important role in T1D management. Although general healthy eating recommendations remain central in diabetes education, there is evidence to support carbohydrate quantification (within 10g of the true value), insulin-to-carbohydrate ratios, low glycaemic index, and modification of and insulin dosing for dietary fat and protein (Bell et al., 2015; Evert et al., 2019; Smart et al., 2020). It is recommended individuals either adopt a 'consistent carbohydrate intake' approach to match fixed mealtime doses of insulin or implement a 'flexible carbohydrate intake' by using individualised insulin-to-carbohydrate ratios, which may also involve insulin dosing for fat and protein (Craig et al., 2011; Smart et al., 2020). Carbohydrate quantity and distribution will depend on the individual's energy requirements, eating patterns, activity levels, and insulin regimen (Craig et al., 2011).

1.2.1.3.3   Monitoring

Intensive therapy (trying to mimic blood glucose levels of those without diabetes) has been shown to reduce the risk of macro- and microvascular complications. Monitoring blood glucose levels is an important component of intensive therapy, allowing individuals to make timely therapeutic decisions in order to achieve glycaemic targets (American Diabetes Association, 2021b; The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Study Research Group, 2016). There are several ways to monitor blood glucose including HbA1c, self-monitoring blood glucose, continuous glucose monitoring (CGM) / intermittently scanned CGM (isCGM) and time in range. HbA1c has the strongest predictive value for diabetes complications and for this reason is the primary tool for measuring glycaemic control (American Diabetes Association, 2021b). The frequency of HbA1c monitoring will depend on the individual's clinical situation but is recommended to be performed at least two to three times a year (American Diabetes Association, 2021b; Craig et al., 2011). Despite its importance, HbA1c is unable to provide real-time feedback to guide treatment decisions on insulin, nutrition, physical activity, and hypoglycaemia prevention; individual glucose monitoring is a crucial adjunct component of standard intensive diabetes management (American Diabetes Association, 2021b; Craig et al., 2011).

Self-monitoring blood glucose and CGM/isCGM are two available options for self-monitoring glucose. Self-monitoring blood glucose uses a small drop of capillary blood to provide a blood glucose reading for that point in time. It is recommended at least four to six times per day but can be more frequent depending on the individual's needs and goals

(American Diabetes Association, 2021b; Craig et al., 2011). Although useful, self-monitoring blood glucose only provides a cross-sectional 'snapshot' of blood glucose levels and may not detect all peaks and troughs in between monitoring (Craig et al., 2011). Continuous glucose monitoring / intermittently scanned continuous glucose monitoring is a complementary method to assess glucose levels. A self-administered sensor is positioned in the interstitial fluid of the arm, buttock, or abdomen and detects interstitial glucose levels every five minutes. This provides an abundance of glucose data, such that glucose trends and therefore predicted glucose can be displayed by the device (American Diabetes Association, 2021c). Used correctly, CGM / isCGM enable timely (and predictive) self-management decisions, contributing to lower HbA1c and reduce episodes of hypoglycaemia (American Diabetes Association, 2021c). The use of time in range from CGM / isCGM devices correlates well with HbA1c and the risk of complications. Time above and below target parameters can also provide useful insight when evaluating treatment regimens (American Diabetes Association, 2021b).

1.2.1.3.4   Physical Activity

Given excess mortality in T1D, management strategies which abate micro- and macrovascular complications play a crucial role in T1D management and mortality. Those who are physically active may experience less micro- and macrovascular complications including retinopathy, microalbuminuria, cardiovascular disease, and experience lower all-cause mortality (Bohn et al., 2015; Chimen et al., 2012; Moy et al., 1993; Tielemans et al., 2013; Wadén et al., 2008; Yardley et al., 2014). Using a cohort of 548 participants, the Pittsburgh Insulin-Dependent Diabetes Mellitus Morbidity and Mortality Study showed that activity is beneficial to longevity and proved to be a strong, independent predictor associated with reduced mortality in males (Moy et al., 1993). Similarly, the EURODIAB Prospective Complications Study found that in a cohort of 3,250 T1D participants, physical activity was inversely associated with all-cause mortality (men and women) and incident cardiovascular disease (women only) (Tielemans et al., 2013). The Finnish Diabetic Nephropathy Study, a cross-sectional analysis of 1,945 individuals with T1D, reported greater frequency and severity of complications among those reporting little leisure-time physical activity versus those with higher activity levels (Wadén et al., 2008). A large cross-sectional study of 18,028 people living with T1D in Germany and Austria found inverse association between self-reported physical activity and body mass index, dyslipidaemia, hypertension, retinopathy, and microalbuminuria (Bohn et al., 2015). Although there is some empirical evidence to suggest regular physical activity may contribute to a reduction in HbA1c, the benefits of physical activity on glycaemic control

are unclear and require further investigation (Chimen et al., 2012; Kennedy et al., 2013; Quirk et al., 2014; Tonoli et al., 2012; Yardley et al., 2014). Further research is also required to confirm indications that physical activity has a positive effect on psychological well-being in people living with T1D (Chimen et al., 2012; Edmunds et al., 2007; Zoppini et al., 2003).

Physical activity is a challenging aspect of diabetes management. It can result in dramatic fluctuations of blood glucose levels as the contracting muscle mobilises insulin independent pathways to the muscle cell. The translocation of glucose transporter (GLUT-4) mediated by muscle contraction during activity, allows glucose to enter the cell without insulin and enhances muscle glycogen storage following activity. This, together with increase glucose uptake by skeletal muscle can result in hypoglycaemia during and up to 48 hours after activity (Teich & Riddell, 2016). Hypoglycaemia is defined as a blood glucose level less than or equal to 3.9 mmol/L (Seaquist et al., 2013). The rate of blood glucose decline will depend on the duration, intensity and type of activity (Tonoli et al., 2012). Conversely, high intensity activity can promote counterregulatory hormone response resulting in high hepatic glucose production. With insufficient insulin onboard, this can result in hyperglycaemia, defined as blood glucose greater than or equal to 15 mmol/L (Craig et al., 2011). Without careful adjustment of insulin and or carbohydrate in response to activity type, intensity, and duration, rapid fluctuations in blood glucose will occur. This complex adjustment requires knowledge, advanced self-management skills, and planning from the person living with T1D (Galassetti & Riddell, 2013).

1.2.1.3.5 Diabetes Self-Management Education

Diabetes self-management education is the facilitation of knowledge, skills, and abilities necessary for diabetes self-management, and is recommended for all those living with T1D (American Diabetes Association, 2021a; Chatterjee, Davies, Heller, et al., 2018). Diabetes self-management education can be delivered in a group, one-on-one, and via telehealth and has moved away from didactic models of care, emphasising instead self-empowerment and self-management using behaviour change theories tailored to the needs of people living with T1D (Young-Hyman et al., 2016). Despite growing evidence that diabetes self-management education has biomedical and psychosocial benefits, uptake is low globally (Chatterjee, Davies, Heller, et al., 2018). In Australia, 49% of the Diabetes MILES survey respondents indicated they had never been offered structured diabetes education (Speight et al., 2011), while only 40% of respondents living with T1D in the Diabetes MILES-2 study had attended group education (Ventura et al., 2016).

Although diabetes self-management education is recommended for all adults living with T1D, health professionals do not always know what to advise patients when it comes to physical activity (Knight et al., 2016). In 2017 a consensus statement on exercise management for T1D was published in an effort to improve and standardise advice given by diabetes health professionals (Michael C. Riddell et al., 2017) and was critical in setting foundations for consistent, evidence-informed education in this area. Behavioural interventions targeting physical activity have been successful in managing and preventing prediabetes, T2D, and in other chronic condition populations including cardiovascular disease, arthritis, chronic obstructive pulmonary disease, and some cancers (Conn et al., 2008; Greaves et al., 2011). These interventions have been shown to improve health outcomes and to be cost effective (Greaves et al., 2011; Lindgren et al., 2007). Despite the availability of clear management guidelines and the success of behavioural interventions in many chronic condition populations, very few interventions have been trialled in the T1D population. This has resulted in a dearth of systematic evidence to inform effective intervention design around physical activity for people living with T1D.

1.3   Purpose of the Research

The purpose of this research was to provide an understanding of the unique barriers and facilitators of physical activity in adults living with T1D and how self-management, group education can be used to address diabetes-specific barriers, specifically fear of hypoglycaemia (FoH). It is set in a pragmatism research paradigm, positioned to solve practical problems in the constantly changing real world (Creswell & Plano Clark, 2018). A systematic scoping review aimed to map the source and quality of existing literature on barriers and facilitators of physical activity in adults living with T1D and provided context to the intervention under investigation, a pre-existing self-management, group education program, Type 1 TACTICS for Exercise©. As far as it has been possible to ascertain from the literature, this is the first theory-driven self-management intervention developed for this purpose. An overview of the intervention and the behaviour change theories that underpinned it, is provided in Sections 3.4 and 4.1. A pragmatic, two-phase, explanatory sequential mixed methods study aimed to evaluate the feasibility, including acceptability, and preliminary efficacy of Type 1 TACTICS for Exercise©, designed to reduce FoH as a barrier to physical activity in adults living with T1D. In the first phase, a pilot RCT was used to explore the feasibility, acceptability, and preliminary efficacy of theory-driven group education in reducing barriers to physical activity in adults living with T1D in Western Australia. In the second phase, focus group interviews were used to better understand and explain the quantitative results (Creswell & Plano Clark, 2018).

The overall research was guided by the following research questions:

1. What are the barriers and facilitators of physical activity participation in adults aged 18 years and over living with T1D in any environment or care setting?

2. Is it feasible to deliver the intervention and is it acceptable to study participants?

3. Are the study procedures and methods feasible to administer and acceptable to study participants?

4. What are the preliminary effects of the intervention and control workshops on FoH as a barrier to physical activity and associated secondary outcomes?

5. What are the lived experiences of the pilot randomised controlled trial (RCT) participants?

1.4   Significance and Impact

Unfortunately, much of the health promotion efforts targeted towards the general population are not equipped to address the complex dynamic experienced by the T1D community. People living with T1D, and their families may not have the confidence to safely participate in community physical activity initiatives, due to the additional demands of their condition (Kennedy et al., 2018). Finding a feasible, acceptable, and effective program to address general and diabetes-specific barriers to physical activity may give people with T1D the skills and confidence they need to engage in whole population physical activity initiatives. Providing a standardised model of care in this field may also improve confidence among diabetes health professionals to discuss physical activity with patients, hence improving access to evidence-informed, structured education. Greater participation in physical activity in this population has been shown to lessen micro- and macrovascular complications, lower all-cause mortality, and may contribute to improved glycaemic control and psychological well-being.

1.5   Thesis Outline

Chapter 1 provides context to the overall research, introduces the research aims and questions, and provides an outline of the thesis.

Chapter 2 includes a published protocol (Brennan et al., 2020) and subsequent systematic scoping review (Brennan, Brown, Ntoumanis, et al., 2021) which aimed to map the

literature on barriers and facilitators of physical activity in T1D. The review protocol provided a peer reviewed framework for the systematic scoping review and allowed the planned approach to be refined and documented. The systematic scoping review provides insights into the source and quality of existing evidence and revealed a gap in the evidence which guided the research methodology. An updated literature search to 1st June 2021 is also provided in this chapter.

Chapter 3 details the mixed methods study design and methodology, and whole-of-study methods which are not detailed elsewhere in the thesis. It includes a narrative article describing the use of behaviour change theory in Type 1 TACTICS for Exercise[©] (Brennan, Leslie, et al., 2021). Human Research Ethics Committee (HREC) approvals are also detailed in this chapter. Quantitative and qualitative methods are individually described in publications presented in Chapter 4.

Chapter 4 presents published quantitative and qualitative methods and outcomes. The publication entitled, *Self-management group education to reduce fear of hypoglycaemia as a barrier to physical activity in adults living with type 1 diabetes: A pilot randomised controlled trial* was published in the Canadian Journal of Diabetes. It describes methodology of the pilot RCT and reports the feasibility, preliminary efficacy, and limited aspects of acceptability of study procedures of the pilot RCT.

The process evaluation publication entitled, *The acceptability of self-management group education to reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes: A mixed methods approach*, also published in the Canadian Journal of Diabetes, describes methodology of focus group interviews, and reports broader aspects of the acceptability of study procedures, and of the intervention and control, including perceived impact on primary and secondary outcomes. This includes the outcomes of focus group interviews and other quantitative methods used to assess acceptability that are not reported in Section 4.1 (Brennan, Albrecht, et al., 2021).

Chapter 5 presents a joint display to illustrate the integrated findings and meta-inferences. It includes a discussion of how the interview data helped to explain and elaborate on the quantitative results relating to acceptability and preliminary efficacy of group self-management education on T1D management for physical activity, and how the integrated findings address the gaps identified in the systematic scoping review. Finally, implications and directions for future research are discussed before concluding remarks.

Chapter 2   Barriers and Facilitators of Physical Activity

Having established the importance, complexity, and poor uptake of physical activity in T1D management (Chapter 1), a thorough systematic search of the literature was required to establish barriers to and facilitators of physical activity in adults living with T1D. An earlier narrative discussion of the literature outlined preliminary and emerging trends relating to barriers to physical activity experienced by adults living with T1D (Brennan & Brown, 2019). The substantial heterogeneity and emerging nature of this literature supported the use of a scoping review. The scoping review methods were planned and justified in a published protocol presented in Section 2.1. The subsequent published systematic scoping review is presented in Section 2.2. Gaps highlighted by this review guided and informed the mixed methods investigation of a theory-driven group education intervention.

2.1   Scoping Review Protocol

Brennan, M., Brown, J., Ntoumanis, N., & Leslie, G. (2020). Barriers and facilitators to
physical activity participation in adults living with type 1 diabetes: A scoping review
protocol. *JBI Database of Systematic Reviews and Implementation Reports*, *18*(0),
1-7. https://doi.org/10.11124/JBISRIR-D-19-00219

SYSTEMATIC   REVIEW   PROTOCOL

Barriers and facilitators to physical activity participation in adults living with type 1 diabetes: a scoping review protocol

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ABSTRACT

Objective: The objective of this scoping review is to identify and map barriers to and facilitators of physical activity in adults living with type 1 diabetes.

Introduction: Physical activity is crucial to the day-to-day management of type 1 diabetes and in the prevention of diabetes-related complications. Despite these benefits, people living with type 1 diabetes have higher inactivity rates than those in the general population. Identifying barriers and facilitators to physical activity, specific to the type 1 diabetes population, may help explain this discrepancy.

Inclusion criteria: This scoping review will include articles describing adults aged 18 years or over, living with type 1 diabetes in any care setting. Included literature will focus on the key concepts under review: barriers to or facilitators of physical activity participation. Literature examining efficacy of strategies to manage blood glucose levels for physical activity will not be included.

Methods: All sources of information will be reviewed, including peer-reviewed, published and unpublished literature. Database search limits will be applied to include articles written in English, involving human participants and published between 1996 and February 2019. Once all records are identified, duplicates will be removed. Remaining records will be subject to title and abstract screening where articles will be excluded if they clearly meet at least one exclusion criteria. All remaining full-text articles will be assessed for eligibility against inclusion and exclusion criteria. Included articles will undergo critical appraisal before being synthesized, charted and discussed.

Keywords barriers; exercise; facilitators; scoping review; type 1 diabetes

Introduction

Type 1 diabetes (T1D) is a complex autoimmune condition characterized by rapid and permanent destruction of insulin-producing pancreatic beta cells.[1,2] The current management of T1D involves permanent exogenous insulin delivery.[1,2] Global prevalence of T1D is difficult to calculate; however, the International Diabetes Federation reports 132,600 new cases of T1D each year in people aged 0–19 years.[3] The National Diabetes Services Scheme (NDSS) estimates that there are approximately 120,000 people in Australia living with T1D, with an estimated average of nine new T1D registrants to the NDSS per day.[4] Although T1D is most commonly diagnosed during childhood and adolescent years, in Australia, 88% of people living with T1D are over the age of 20 and 63% are over the age of 40.[4,5] Effective management of T1D involves exogenous insulin delivery and carbohydrate adjustment in an effort to maintain euglycemia.[2] In addition, physical activity is now considered a mainstay component of ongoing T1D management.[6]

Although the terms "physical activity" and "exercise" are often used interchangeably, they do carry distinct meanings. The World Health Organization[7] and Caspersen *et al.*[8] describe physical activity as

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any bodily movements that are done as part of work, play, transport, housework and/or recreational activities. Exercise is a subcategory of physical activity and is defined as structured, planned and purposeful activity to improve or maintain components of fitness.[7] In addition to general health benefits, physical activity has been shown to reduce insulin requirements, reduce cardiovascular risk, improve well-being and reduce all-cause mortality in those living with T1D.[9] In order to gain these benefits, people living with T1D are encouraged to limit sitting time, participate in 150 minutes of moderate-intensity physical activity per week, and include resistance training on two days per week.[10]

Despite clear recommendations and benefits of physical activity, literature from around the world indicates higher levels of inactivity in the T1D population when compared to general populations.[11-13] In Australia, the Diabetes MILES study found that 65% of adults who are aged between 18 and 65 years and living with T1D were not meeting physical activity guidelines, compared to 52% of the general population.[14] A multicenter study conducted in Germany and Austria found that 82% of T1D participants were not participating in physical activity on more than two days per week.[11] By comparison, rates of inactivity amongst the general German population have been reported at approximately 61% of adults not meeting the recommended 30 minutes of moderate intensity activity on five or more days of the week.[15] In the USA, 67% of people living with T1D were not meeting physical activity recommendations,[12] compared with 48% in the general population.[16] In Canada, an earlier study found that 68% of T1D study participants were not meeting Canadian physical activity recommendations, compared to 58% in the general population.[13] Although it is likely that people living with T1D experience similar barriers to physical activity as the general population, these higher rates of inactivity suggest there may be additional considerations for the person living with T1D.

Although beneficial to the long-term health of people living with T1D, physical activity can present some challenges for this population.[17,18] Physical activity can lead to dramatic fluctuations in blood glucose level (BGL).[6,9] Of most concern is hypoglycemia or low BGL, defined as BGL less than 4 mmol/L.[2] Blood glucose response to physical activity can be varied depending on the type, duration

and intensity of activity, complicating the already challenging task of managing BGL day to day.[6] Given the complexity of managing T1D and physical activity, planning and specific skills to manage BGL are required by the person living with the condition.[6] Existing physical activity promotion campaigns in the general population may not be adequate or suitable for the T1D community given the unique challenges they may face.

A preliminary, narrative discussion of the literature revealed an emerging base of literature outlining commonly reported T1D specific barriers and a gap in evidence-informed interventions to address these specific barriers.[19] This narrative review has informed the proposed scoping review and it intends to formally map the emerging evidence on barriers to and facilitators of physical activity in T1D. A limited search of the literature outlined substantial heterogeneity among a small number of studies, further justifying a scoping review of the literature.[19] This scoping review will identify gaps in the evidence as well as provide initial insights into the quality and source of existing evidence. This information will be crucial to understanding the barriers faced by people living with T1D, as well as guiding future research and interventions to address these barriers.

A preliminary search of PROSPERO, the Cochrane Database of Systematic Reviews and the *JBI Database of Systematic Reviews and Implementation Reports* was conducted, and no current or planned scoping reviews or systematic reviews on the topic were identified.

The objective of this scoping review is to identify and map barriers to and facilitators of physical activity in adults living with T1D in any care setting or environment.

Review question

What are the barriers to and facilitators of physical activity participation in adults aged 18 years and over who are living with T1D in any environment or care setting?

Inclusion criteria
Participants

This review will consider studies that involve participants of any gender, over the age of 18 years who are living with T1D. Further clarification will be sought from authors where details cannot be extracted and interpreted independently. For

example, in a study with a sample including participants with both type 1 and type 2 diabetes, where details specific to the T1D participants cannot be extracted, the reviewers will attempt to contact the authors. If such detail cannot be obtained, the study will not be included.

Concept

This review will consider studies that explore barriers to physical activity participation or facilitators of physical activity participation.

The concept "barriers to physical activity" will include qualitative and quantitative methods of assessment. This concept will also incorporate studies exploring problems, issues, challenges, and/or difficulties with physical activity participation.

The concept "facilitators of physical activity" will refer to the implementation of guidelines or recommendations as interventions or programs. The authors acknowledge that there is literature examining the most effective methods to manage BGL for physical activity; however, this information is outside the scope of this review. As such, the review is focused on the methods used to facilitate participation in physical activity rather than glycemic control. The review will include studies that examine physical activity participation or intention to participate in physical activity as outcomes. Where fitness or glycemic biomarkers (for example, glycated hemoglobin) are the only reported outcome measures, the study will be excluded. Sources examining correlated or associated factors to physical activity participation (for example, psychosocial factors or use of diabetes technology such as insulin pumps or continuous glucose monitoring) will be included, as these factors may influence barriers and facilitators.

Context

Studies that occur in any care settings in any geographical location will be considered in this review.

Type of sources

Primary research reports using quantitative, qualitative and mixed-methods study designs will be considered for inclusion. In addition, systematic reviews and text and opinion papers will be considered for inclusion. Articles published in English will be included. Articles published from 1996 to the present will be included as the first analog insulin, Lispro, was approved by the USA's Food and Drug

Authority in 1996.[20] Lispro changed the course of diabetes management for people with T1D.[21] More flexibility in dosing and less nocturnal hypoglycemia was observed with the introduction of Lispro; these are important factors in managing BGL for physical activity.[21] Articles will be excluded where full-text copies cannot be obtained.

Methods

The proposed review will be conducted in accordance with the JBI methodology for scoping reviews.[22]

Search strategy

An initial limited search of MEDLINE and CINAHL was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles, were used to develop a full search strategy for MEDLINE (see Appendix I). An experienced university librarian has been consulted (and will continue to be consulted) during this search phase. The search strategy, including all identified keywords and index terms, will be adapted for each included information source. The reference list of all studies selected for critical appraisal will be screened for additional studies meeting the inclusion criteria, which will then be included in the review.

Information sources

The databases to be searched include CINAHL full text (EBSCO), MEDLINE (Ovid), Web of Science (Clarivate Analytics), Scopus (Elsevier), PsycINFO (Ovid) and PubMed (NCBI). Sources of unpublished studies and gray literature to be searched will be guided by the Canadian Agency for Drugs and Technologies in Health (CADTH) checklist.[23] Additional sources to be searched that do not appear on the CADTH checklist will include government health websites (Australian National Diabetes Strategy), The Australian Centre for Behavioural Research in Diabetes, Exercise and Sports Science Australia, and Australian Diabetes Educator. Given the iterative nature of searching gray literature, additional sources may also be searched as they are discovered.

Study selection

Following the search, all identified records will be collated and uploaded into EndNote X9 1.1 (Clarivate Analytics, PA, USA) and duplicates removed. Titles and abstracts will then be screened by two

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independent reviewers for assessment against the inclusion criteria for the review. Potentially relevant papers will be retrieved in full and their citation details imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI; JBI, Adelaide, Australia).[24] The full text of selected citations will be assessed in detail against the inclusion criteria by two independent reviewers (MB and JB). Reasons for exclusion of full-text studies that do not meet the inclusion criteria will be recorded and reported in the review. Any disagreements that arise between the reviewers at each stage of the study selection process will be resolved through discussion, or with a third reviewer (GL). The results of the search will be reported in full in the final review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.[25]

Assessment of methodological quality

Although an optional item in the PRISMA-ScR guide, the review team has opted to include critical appraisal in the proposed scoping review.[26] The decision to include critical appraisal was made in order to report on the quality of existing research to guide future researchers. Eligible studies will be critically appraised by two independent reviewers (MB and JB) at the study level for methodological quality in the review using standardized critical appraisal instruments from the JBI for observational, text and opinion, qualitative, experimental, quasi-experimental studies.[22] Authors of papers will be contacted to request missing or additional data for clarification, where required. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer (GL). As a minimum, included studies will be peer-reviewed, use appropriate statistical analysis, and have obtained ethics approval (or in the case of text and opinion pieces,[22] the source of the opinion has standing in the field of expertise). All studies meeting this minimum quality threshold will undergo data extraction and synthesis (where possible). Results of the critical appraisal will be tabulated to show the percentage of criteria met by each study and will be discussed in narrative form.

Data extraction

Data will be extracted from papers included in the scoping review by two independent reviewers using a data extraction tool developed by the reviewers. The data extracted will include specific details about the population, concept, context, study methods, and key findings relevant to the review objective.

A draft charting table is provided and includes minor revisions to the original JBI template (see Appendix II).[22] Revisions include examples of details/results extracted from study to align with the concepts of the scoping review. The draft data extraction tool will be modified and revised as necessary during the process of extracting data from each included study. The review team will trial the charting table on two or three studies to ensure that all relevant results are extracted.[22] Modifications will be detailed in the full scoping review report. Any disagreements that arise between the reviewers will be resolved through discussion, or arbitrated by a third reviewer. Authors of papers will be contacted to request missing or additional data, where required.

Data presentation

The extracted data will be presented in tabular form in a manner that aligns with the objective of the scoping review. A narrative summary will accompany the tabulated results and will describe how the results relate to the review's objective and question.

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Appendix I: Search strategy

MEDLINE (Ovid). Search conducted on 26 February 2019.

	Search	Records retrieved
1	exp Exercise/	178,979
2	exp Physical Fitness/	27,416
3	exp Sports/	171,879
4	"physical activity".mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	98,573
5	1 or 2 or 3 or 4	322,755
6	exp Health Education/	232,925
7	Patient Education as Topic/	82,071
8	exp Health Promotion/	72,284
9	Health Knowledge, Attitudes, Practice/	103,119
10	("group education" or "group program" or "group intervention" or "program*" or "counsel?ing" or "strategy*" or "facilitators" or "method*" or "motivators" or "enablers").mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	9,107,305
11	6 or 7 or 8 or 9 or 10	9,229,386
12	Diabetes Mellitus, Type 1/	72,529
13	"insulin dependent diabetes mellitus".mp.	15,585
14	12 or 13	80,670
15	("barriers to physical activity" or "barriers" or "problems" or "challenges" or "issue*" or "difficult*" or "compliance" or "non?compliance").mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	1,923,465
16	"associat*" OR "predictors" OR "correlat*" OR "links" (Including Related Terms)	6525
17	16 or 15 or 11	10,154,408
18	5 and 14 and 17	1028
19	limit 18 to (english language and humans and yr = "1996 - 2019")	800

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Appendix II: Data extraction instrument

Scoping review details	
Scoping review title:	
Review objective/s:	
Review question/s:	
Inclusion/Exclusion criteria	
Population	
Concept	
Context	
Types of study	
Study details and characteristics	
Study citation details (e.g. author/s, date, title, journal, volume, issue, pages)	
Country	
Context	
Participants (details e.g. age/sex and number)	
Details/Results extracted from study (in relation to the concept of the scoping review)	
Barriers to physical activity participation	
Tools used to measure barriers	
Associations or correlations (physical activity)	
Facilitator of physical activity	
Measure of physical activity participation	

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2.2   Systematic Scoping Review

The following published systematic scoping review was conducted and reported in accordance with the protocol presented in Section 2.1 (Brennan et al., 2020), with the exception of the following minor deviations:

Data extraction tool: The data extraction tool reported in Appendix A of the review varies from the proposed tool detailed in Appendix II of the protocol. However, deviation was predicted and described in the scoping review protocol, with the draft data extraction tool modified and revised as necessary during the process of extracting data from each included article (Peters et al., 2017). Three fields were added after trialling the tool on three articles: aim / hypothesis / objectives, recruitment methods, and key findings.

Minimum quality threshold: The protocol indicated that a minimum quality threshold would be enforced. It was proposed that articles would, at a minimum, be peer reviewed, use appropriate statistical analysis, and have obtained ethics approval (or in the case of text and opinion pieces, the source of the opinion had standing in the field of expertise) (Brennan et al., 2020). Enforcing the minimum quality threshold was proposed to ensure included articles were of an adequate scientific standard for review. Upon commencing the systematic scoping review and reflecting on its aim, the authors re-evaluated the relevance of a minimum quality threshold. To ensure a full representation of the current literature and to align with the purpose of the review, quality appraisal was conducted but a minimum quality threshold was not enforced in the systematic scoping review. This highlighted the vast variation in methodological rigour among included articles; an important and useful finding to guide future research in the area.

Data presentation: The protocol stated that data would be presented in tabular form. After several iterations of a table which did not allow clear interpretation of the data, a mind map was deemed to be the most suitable and impactful way to present and interpret the data.

Brennan, M. C., Brown, J. A., Ntoumanis, N., & Leslie, G. D. (2021). Barriers and facilitators of physical activity participation in adults living with type 1 diabetes: A systematic scoping review. *Applied Physiology, Nutrition, and Metabolism, 46*(2), 95-107. https://doi.org/10.1139/apnm-2020-0461

NRC Research Press

SYSTEMATIC REVIEW

Barriers and facilitators of physical activity participation in adults living with type 1 diabetes: a systematic scoping review

Marian C. Brennan, Janie A. Brown, Nikos Ntoumanis, and Gavin D. Leslie

Abstract: To identify and map barriers and facilitators of physical activity (PA) in adults living with type 1 diabetes (T1D) in any care setting or environment. A scoping review was conducted in accordance with the PRISMA-ScR guidelines to address the aim of this review. Exclusion/inclusion criteria were determined a priori. Articles captured in the search were subject to title and abstract screening before full-text articles were assessed for eligibility against the exclusion/inclusion criteria. Included articles underwent critical appraisal before being charted, mapped, and discussed. Forty-six articles were included in the final synthesis. Most commonly, articles reported cross-sectional survey studies (46%), then qualitative designs (17%), and opinion or text (17%). Experimental studies accounted for 13% of included articles. *Hypoglycaemia/fear of hypoglycaemia* was the most commonly reported barrier and *patient education* the most commonly discussed facilitator. Quality appraisal revealed methodological issues among included articles. Higher quality research with theoretically sound behaviour-change interventions combined with targeted patient education is needed to address hypoglycaemia/fear of hypoglycaemia as a barrier to PA.

Novelty:

- Hypoglycaemia and fear of hypoglycaemia were the most commonly reported barriers to PA in adults with T1D.
- Powered randomised controlled trials are required to establish efficacy of behaviour change interventions targeting these barriers to PA.

Key words: adult, barriers, exercise, facilitators, scoping review, type 1 diabetes.

Résumé : Cette étude se propose d'identifier et de cartographier les obstacles et les facilitateurs de l'activité physique (« PA ») chez les adultes aux prises avec le diabète de type 1 (« T1D ») dans tout milieu de soins ou autre. Un examen de la portée est réalisé conformément aux directives de PRISMA-ScR pour répondre au but de cette étude. Les critères d'exclusion/inclusion sont déterminés a priori. Les articles relevés dans la recherche font l'objet d'une sélection de titre et de résumé avant que les articles en texte intégral ne soient évalués pour leur admissibilité au regard des critères d'exclusion/inclusion. Les articles inclus font l'objet d'une évaluation critique avant d'être inscrits dans un tableau, cartographiés et discutés. Quarante-six articles sont inclus dans la synthèse finale. Le plus souvent, les articles font état d'enquêtes transversales (46 %), puis de plans qualitatifs (17 %) et d'opinions ou de textes (17 %). Les études expérimentales représentent 13 % des articles inclus. *L'hypoglycémie et la peur de l'hypoglycémie* constituent les obstacles les plus souvent évoqués et *l'éducation des patients* est le facilitateur le plus souvent abordé. L'évaluation de la qualité révèle des problèmes méthodologiques parmi les articles inclus. Des recherches de meilleure qualité avec des interventions de changement de comportement théoriquement cohérent combinées à une éducation ciblée des patients sont requises pour lutter contre *l'hypoglycémie et la peur de l'hypoglycémie* en tant qu'obstacle à la PA. [Traduit par la Rédaction]

Les nouveautés :

- L'hypoglycémie et la peur de l'hypoglycémie sont les obstacles à l'activité physique les plus fréquemment évoqués chez les adultes aux prises avec le T1D.
- Des essais randomisés contrôlés de puissance adéquate sont requis pour établir l'efficacité des interventions de changement de comportement ciblant ces obstacles à l'activité physique.

Mots-clés : adulte, obstacles, activité physique, facilitateurs, examen de la portée, diabète de type 1.

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Introduction

Physical Activity (PA) has long been recommended to people living with type 1 diabetes (T1D), owing to its positive effects on HbA1c, cardiovascular health, and insulin-dose requirements (Yardley et al 2014). PA is included as an essential management strategy in recommendations by various international bodies (Colberg et al. 2016; Craig et al. 2011; Diabetes Canada Clinical Practice Guidelines Expert Committee et al. 2018; National Institute for Health and Care Excellence 2018). It is recommended that people living with T1D engage in at least 150 min per week of moderate-intensity PA, participate in resistance training on 2 days per week, and limit sitting time (Colberg et al. 2016).

Despite the benefits of PA, rates of inactivity in the T1D population are higher than those found in the general population. Internationally, studies have acknowledged 65% to 82% of T1D study participants did not meet national PA guidelines, compared with between 48% to 61% in the general population (Bohn et al. 2015; Clarke et al. 2017; McCarthy et al. 2016; Plotnikoff et al. 2006; Speight et al. 2011; World Health Organization 2016). Both groups are likely to share similar barriers to PA; however, the reported higher rates of inactivity for people living with T1D suggest there may be additional considerations.

PA is a challenging aspect of diabetes management as it can result in dramatic fluctuations of blood glucose levels during and up to at least 24 h after activity. The rate that blood glucose rises or falls depends on the duration, intensity, and type of activity. Without careful adjustment of insulin and/or carbohydrate in response to these factors, rapid fluctuations in blood glucose can occur, often resulting in hyper- or hypoglycaemia (Riddell et al. 2017b). This complex adjustment requires knowledge, well-developed self-management skills, and planning from the person living with T1D. It is conceivable that people living with T1D may choose to avoid PA to obviate the unpleasant extremes of hyper- and hypoglycaemia. These unique challenges are not addressed by generic, whole-population PA campaigns, nor programs targeting non-specific diabetes cohorts.

Systematic reviews in the area of T1D and PA participation in the past decade have largely focussed on child and adolescent populations (Pillay et al. 2015). We identified 1 systematic review that examined diabetes self-management education programs, targeting several self-management behaviours and outcomes in T1D participants of all ages (Pillay et al. 2015). The review concluded there was insufficient strength of evidence to comment on PA outcomes in the adult population. We did not locate any systematic reviews synthesising literature on barriers to PA and facilitators specifically targeting PA behaviour in the adult T1D population.

Our scoping review aimed to systematically map the literature on barriers and facilitators of PA in T1D. We elected to conduct a scoping review because of the emerging nature of this field as well as the heterogeneity among a small number of studies identified in previous limited searches of the literature (Brennan and Brown 2019). This review will provide initial insights into the source and quality of existing evidence as well as identify gaps in the evidence. We aimed to provide a better understanding of the issues faced by people living with T1D to guide future research and interventions to support PA in the T1D population.

Review question

What are the barriers and facilitators of PA participation in adults aged 18 years and over living with T1D in any environment or care setting?

A preliminary search of PROSPERO, the Cochrane Database of Systematic Reviews, and the Joanna Briggs Institute (JBI) Database of Systematic Reviews and Implementation Reports was conducted, and no current or planned scoping reviews or systematic reviews exclusively exploring PA participation in T1D were found. Subsequently, this review was registered with the JBI database in February 2019 and has been executed in accordance with the following protocol: JBISRIR-D-19-00219R1 (Brennan et al. 2020).

Methods

This review was conducted and reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist (Tricco et al. 2018) (reported in Supplementary Table S1[1]) and the JBI methodology for scoping reviews (Peters et al. 2020). The PRISMA-ScR checklist explains that critical appraisal of included articles is an optional item of the checklist, which is a view shared by JBI (Peters et al. 2020; Tricco et al. 2018). We have opted to include critical appraisal to provide the reader with a better understanding of the reliability, rigour, and overall standing of included articles.

Selection criteria

Concepts

Articles that explored *barriers to PA participation* and/or *facilitators of PA participation* were considered for inclusion in this review. *Barriers to PA* as a concept incorporated articles exploring problems, issues, challenges, and/or difficulties with PA participation. The concept *facilitators of PA* referred to programs, interventions, or factors that may improve PA participation.

We acknowledge that there is literature examining effective methods to manage blood glucose levels for PA; however, these are outside the scope of this review. Our focus was on barriers to and facilitators of participation in PA rather than to achieve glycaemic control. Our review included articles that examined PA participation or intention to participate in PA as outcomes. Where fitness or glycaemic biomarkers (for example, glycated haemoglobin) were the only reported outcome measures, the study was excluded.

Context

Studies or articles that sampled from all care settings, including in-patient, out-patient, primary care, and/or community settings were considered in this review. Articles were not excluded based on geographical location.

Population

Articles sampled participants of any sex, over the age of 18 years, living with T1D. Further clarification was sought from authors where details, specific to these participant features, could not be extracted and interpreted independently. If such clarification could not be obtained, the article was excluded. By way of example, for a study with a sample including participants with both T1D and type 2 diabetes, we sought to obtain details specific to the T1D participants.

Types of sources

Articles reporting research using quantitative, qualitative, and mixed methods study designs were considered for inclusion, as were systematic reviews and text and opinion papers. Articles were limited to those published in English between 1996 to March 2020, as the first analogue insulin was approved in 1996, which subsequently changed the course of T1D management (Quianzon and Cheikh 2012). Every attempt was made to source full-text copies of articles by searching the University library catalogue, journal archives, Google and Google Scholar, as well as contacting authors where contact details were provided. Articles were excluded when full text copies could not be obtained.

Search strategy and article selection

An experienced university health librarian was consulted during the search phase. Using key words from the review question (type 1 diabetes; PA; barriers; correlates; facilitators), an initial limited search of MEDLINE (Ovid) and CINAHL full text (EBSCO) was undertaken. Text words contained in the titles and abstracts of relevant records found in MEDLINE and CINAHL and the index terms were used to develop a full search strategy (Supplementary Table S2[1]). The search strategy was adapted for each of the following searched information sources: CINAHL full text (EBSCO), MEDLINE (Ovid), Web of Science (Clarivate Analytics), Scopus (Elsevier), PsychINFO (Ovid), and PubMed (National Center for Biotechnology Information (NCBI)). Guided by the Canadian Agency for Drugs and Technologies in Health (CADTH) Checklist (Canadian Agency for Drugs and Technologies in Health 2018), we searched sources of unpublished literature and grey literature. Additional sources searched, which did not appear on the CADTH Checklist, included government health websites (Australian National Diabetes Strategy), The Australian Centre for Behavioural Research in Diabetes, Exercise and Sports Science Australia, and the Australian Diabetes Educator publication. The reference lists of all articles selected for critical appraisal were screened for additional articles meeting the inclusion criteria.

Following the search, all identified articles were collated and uploaded into EndNote X9 1.1 (Clarivate Analytics, Pa., USA), and duplicates were removed. As per the PRISMA-ScR checklist (Moher et al. 2009), titles and abstracts were then screened by 2 independent reviewers for assessment against the inclusion/exclusion criteria for the review. Remaining articles were then retrieved in full and their citation details imported into the Joanna Briggs Institute System for the Unified Management, Assessment and Review of Information (JBI SUMARI) (Joanna Briggs Institute, Adelaide, Australia) (Munn et al. 2019). These full-text articles were assessed for eligibility by the same 2 independent reviewers (M.B. and J.B.). Corresponding authors were contacted when clarification was necessary. Reasons for exclusion of full-text articles that did not meet the inclusion criteria were recorded and reported; any disagreements that arose between the reviewers at each stage of the article selection process were resolved through discussion or referral to a third reviewer if required.

Assessment of methodological quality

Eligible articles were critically appraised by 2 independent reviewers for methodological quality using standardised critical appraisal instruments from the JBI for observational, review, text and opinion pieces, qualitative, experimental, and quasi-experimental studies (JBI 2017). Questions within each critical appraisal tool attracted a score of 1 (reflecting the criterion was met) or zero (reflecting either the criterion was not met, or it was unclear to the reviewers). The maximum score corresponds to the number of questions excluding those marked *not applicable* (N/A). Disagreement resolution followed the process explained in article selection. A constellation of critical appraisal tables can be viewed in Supplementary Tables S3.1 to S3.6.[1] A minimum quality threshold for article inclusion was not enforced.

Data extraction and presentation

Data were extracted from included papers using a customised extraction instrument that we developed (Supplementary Table S4[1]). The review team trialled the data extraction tool detailed in the review protocol (Brennan et al. 2020) on 6 articles to ensure all relevant results were extracted (Peters et al. 2020). Modifications included adding "study aims", "recruitment methodology", and "intervention/control" (where appropriate), while definitions of each of these headings were refined.

The extracted data are presented in tabular and diagrammatic (mind map) form in a manner that aligns with the aim of this scoping review. Characteristics of each article, including study design, sample size, concepts explored, and critical appraisal score, are described in Table 1. Individual sources of evidence are presented (Supplementary Table S5[1]), describing the aims, design, participants or population, intervention and/or control, and key findings of each article. The mind map synthesises the literature by grouping barriers and facilitators of PA (Tricco et al. 2018). Included articles may have examined 1 or a combination of these concepts; therefore, the totals included in the mind map may not equate to the number of articles included. All individually reported barriers and facilitators of PA were listed prior to establishing and grouping like list items within each concept. For each barrier and facilitator group, the size of the mind map bubble is influenced by the number of articles that identified this group. An indication is provided for each barrier group as to the portion of articles using quantitative, qualitative, or opinion outputs, or in the case of *facilitators*, themes that were trialled versus suggested. Trialled facilitators used experimental designs to empirically derive efficacy and suggested facilitators were proposed by authors as potential facilitators.

Results

Article inclusion

Databases were searched on 3 February 2020 and identified 4792 records – see adapted PRISMA flow diagram in Fig. 1. The corresponding authors of 7 individual papers were contacted to request missing or additional data for clarification. Three authors replied to this request, none of whom provided information sufficient for inclusion. We were unable to contact the remaining 4 authors. A total of 46 articles were included in the final synthesis.

Characteristics of included articles

Of the 46 articles included in this review, all were placed in the community setting, 11 (24%) of which were more specific in detailing their location as community out-patient clinics. Most were located in the United Kingdom ($n = 11$, 24%), Canada ($n = 10$, 22%), and the United States ($n = 9$, 20%). Table 1 shows most commonly, articles reported cross-sectional survey studies (46%), followed by qualitative designs (17%), and opinion or text (17%). For those studies that included research participants, sample size ranged from 4 to 1104. Studies of experimental design (3 randomised control trials and 3 quasi-experimental) had an average sample size of 34. A total of 37 (80%) articles focussed on *facilitators* and 24 (52%) articles examined *barriers* to PA. Full details of included individual sources of evidence are provided in Supplementary Table S5.[1]

Critical appraisal

The results of the critical appraisal are tabulated to show each criterion met by the included article (Supplementary Tables S3.1 to S3.6[1]). The critical appraisal tables are sequenced to reflect a hierarchy of evidence from *systematic reviews* to *text and opinion*. Higher scores within each table correspond to greater methodological quality within the hierarchical category.

Included within the highest level of evidence, i.e., systematic reviews (Supplementary Table S3.1[1]), were 2 studies (Kavookjian et al. 2007; Pillay et al. 2015) that scored 8/11 and 10/11, respectively. Randomised control trials (RCTs) followed (Supplementary Table S3.2[1]), where 3 included studies (Brazeau et al. 2014; Hasler et al. 2000; Narendran et al. 2017) scored 3/13 (Hasler et al. 2000) and 2 studies scored 9/13 (Brazeau et al. 2014; Narendran et al. 2017). There were 3 quasi-experimental studies (Dyck et al. 2018; Ruiz-González et al. 2016; Scott et al. 2019) that scored 3/6, 7/9, and 3/6, respectively (Supplementary Table S3.3[1]). The majority (21) of included

Table 1. Article characteristics.

Study/reference	Design	Sample size or no. of studies (reviews only)	Concepts		Critical appraisal score
			Barriers	Facilitators	
Kavookjian et al. (2007)	Systematic review	41	—	Patient education (unspecified)	8/11
Klaprat et al. (2019)	Narrative review	NR	—	Patient education (unspecified)	3/11
Pillay et al. (2015)	Systematic review	36	—	Patient education (unspecified)	10/11
Brazeau et al. (2014)	RCT	48	—	Patient education (group) Exercise programs (group)	9/13
Hasler et al. (2000)	RCT	34	—	Patient education (1:1) Psychosocial factors (stage of change)	3/13
Narendran et al. (2017)	RCT	58	—	Patient education (1:1) Positive biomarkers ($\dot{V}O_{2max}$)	9/13
Dyck et al. (2018)	Quasi-experimental	12	Hypo/FoH Time/energy/motivation/work Low fitness/tired BGL variability/loss of control	Patient education (group) Exercise programs (group)	3/6
Ruiz-González et al. (2016)	Quasi-experimental	40	—	Patient education (group)	7/9
Scott et al. (2019)	Quasi-experimental	11	Hypo/FoH Time/energy/motivation/work	Technology (phone app) Exercise programs (1:1)	3/6
Ahola et al. (2012)	Cross-sectional	1104	—	Psychosocial factors (sense of coherence)	6/8
Ahola et al. (2016)	Cross-sectional	615	Hypo/FoH (not significant)	Hypo/FoH (not significant)	2/8
Brazeau et al. (2008)	Cross-sectional	100	Hypo/FoH Time/energy/motivation/work Low fitness/tired BGL variability/loss of control	Psychosocial factors (well-being; social support) Guidelines/increase patient knowledge	5/8
Delmonte et al. (2013)	Cross-sectional	33	Islet cell transplant (not significant)	Islet cell transplant (not significant)	5/7
Duarte et al. (2012)	Cross-sectional	107	Hypo/FoH Time/energy/motivation/work Psychosocial factors (discouragement)	—	5/8
Kebede and Pischke (2019)	Cross-sectional	1052	—	Technology (phone app)	6/8
Keshawarz et al. (2018)	Cross-sectional	44	Hypo/FoH BGL variability/loss of control Hyperglycaemia Technology (CGM) Demographics (younger age)	Positive biomarkers (high HDL; lower diastolic blood pressure)	5/8
Kneckt et al. (2001)	Cross-sectional	149	—	Psychosocial factors (self-esteem)	6/8
Lloyd et al. (2010)	Cross-sectional	264	Psychosocial factors (diabetes distress)	—	7/8
Martyn-Nemeth et al. (2017)	Cross-sectional	35	Hypo/FoH	—	5/8
McCarthy et al. (2017)	Cross-sectional	83	Hypo/FoH Time/energy/motivation/work Environment (weather)	Demographics (full-time work)	6/8
Pinsker et al. (2016)	Cross-sectional	244	Technology (pump)	—	3/8
ALEXANDRA Study – Plotnikoff et al. (2010a)	Cross-sectional	697	—	Psychosocial factors (perceived behavioural control)	6/7
ALEXANDRA Study – Plotnikoff et al. (2009)	Cross-sectional	695	Diagnosis of T1D	Patient education (unspecified) HP training and engagement Overcoming barriers/trial and error	6/7
ALEXANDRA Study – Plotnikoff et al. (2007)	Cross-sectional	510	Difficulties with ADLs Demographic factors (older age)	Less perceived disability/ADL difficulties Demographic factors (younger age at diagnosis)	5/7

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Table 1 (continued).

Study/reference	Design	Sample size or no. of studies (reviews only)	Concepts		Critical appraisal score
			Barriers	Facilitators	
ALEXANDRA Study – Plotnikoff et al. (2010b)	Cross-sectional	697	—	Psychosocial factors (intention; self-efficacy)	6/7
ALEXANDRA Study – Plotnikoff et al. (2006)	Cross-sectional	697	—	Less perceived disability/ADL difficulties. Demographic factors (younger age; single; higher income)	7/8
ALEXANDRA Study – Plotnikoff et al. (2008)	Cross-sectional	697	—	Psychosocial factors (self-efficacy) Time management/goal setting	6/7
Raaijmakers et al. (2015)	Cross-sectional	143	Demographic factors (higher education)	—	6/8
Stuij et al. (2017)	Cross-sectional	71	Limited HP support or advice	—	2/8
Thomas et al. (2004)	Cross-sectional	77	Age or weight (not significant)	Age or weight (not significant)	2/8
Balfe et al. (2014)	Qualitative	32	Time/energy/motivation/work. Low fitness/tired. Environment (bad weather)	Psychosocial factors (social support; motivation) Environment (good weather)	6/10
Dizon et al. (2019)	Qualitative	21	—	HP training and engagement. Psychosocial factors (social support). Technology (phone app). Overcoming barriers/trial and error	8/10
Kennedy et al. (2018)	Qualitative	15	Hypo/FoH. Time/energy/motivation/work. Limited HP support or advice. Lack of knowledge. Psychosocial factors (low confidence). Diagnosis of T1D	Patient education (group). Exercise programs (group). Time management/goal setting	6/10
Kilbride et al. (2011)	Qualitative	4	—	Psychosocial factors (locus of control). Guidelines/increase patient knowledge. Overcoming barriers/trial and error. Reduce FoH	6/10
Kime et al. (2018)	Qualitative	67	Hypo/FoH. Time/energy/motivation/work. Psychosocial factors (embarrassment)	Patient education (group). HP training and engagement. Psychosocial factors (social support; enjoyment). Guidelines/increase patient knowledge. Exercise programs (group)	8/10
Lascar et al. (2014)	Qualitative	26	Time/energy/motivation/work. Lack of knowledge. Psychosocial factors (embarrassment). Environment (weather)	Psychosocial factors (social support; enjoyment). Guidelines/increase patient knowledge. Time management/goal setting. Environment (free/reduced admission to gyms/pools)	6/10
Martyn-Nemeth et al. (2019)	Qualitative	30	Hypo/FoH. Time/energy/motivation/work	Overcoming barriers/trial and error	8/10
Oser et al. (2019)	Qualitative	67 blog posts + 10 participants	Hypo/FoH. Time/energy/motivation/work. Limited HP support or advice	HP training and engagement. Psychosocial factors (social support). Exercise programs (unspecified)	7/10
Colberg et al. (2015)	Text and opinion	Nil	Hypo/FoH. Lack of knowledge	Technology (activity trackers; pumps; glucose monitors; CGM; artificial pancreas; social integration)	5/5

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Table 1 (concluded).

Study/reference	Design	Sample size or no. of studies (reviews only)	Concepts		Critical appraisal score
			Barriers	Facilitators	
Greener (2017)	Text and opinion	Nil	Hypo/FoH	Guidelines/Increase patient knowledge	5/6
			Limited HP support or advice	Time management/goal setting	
			BGL variability/loss of control		
			Lack of knowledge		
Kime and Pringle (2018)	Text and opinion	Nil	—	Patient education (unspecified)	5/6
Kime and Pringle (2019)	Text and opinion	Nil	Limited HP support or advice	HP training and engagement	4/6
Narendran and Andrews (2018)	Text and opinion	Nil	Hypo/FoH	Patient education (unspecified)	6/6
			Time/energy/motivation/work	HP training and engagement	
			Limited HP support or advice	Psychosocial factors (social support)	
			BGL variability/loss of control		
			Lack of knowledge		
			Psychosocial factors (overwhelmed; low confidence)		
National Institute for Health and Care Excellence (2018)	Text and opinion	Nil	—	HP training and engagement	5/5
				Guideline/increase patient knowledge	
Riddell et al. (2017a)	Text and opinion	Nil	Limited HP support or advice	Patient education (group)	6/6
				HP training and engagement	
				Overcoming barriers/trial and error	
Sundberg (2018)	Text and opinion	Nil	Psychosocial factors (low confidence)	Patient education (unspecified)	5/5
				Reduce FoH	

Note: 1:1, one-on-one delivery; ADL, activities of daily living; BGL, blood glucose level; CGM, continuous glucose monitor; FoH, fear of hypoglycaemia; Group, delivered in a group setting; HDL, high-density lipoprotein; HP, health professional; hypo, hypoglycaemia; NR, not reported; PA, physical activity; RCT, randomised controlled trial; Unspecified, unspecified mode of delivery; VO_{2max}, maximal oxygen uptake.

studies were cross-sectional survey designs (Ahola et al. 2012, 2016; Brazeau et al. 2008; Delmonte et al. 2013; Duarte et al. 2012; Kebede and Pischke 2019; Keshawarz et al. 2018; Kneckt et al. 2001; Lloyd et al. 2010; Martyn-Nemeth et al. 2017; McCarthy et al. 2017; Pinsker et al. 2016; Plotnikoff et al. 2006, 2007, 2008, 2009, 2010a, 2010b, Raaijmakers et al. 2015; Stuij et al. 2017; Thomas et al. 2004) (Supplementary Table S3.4[1]) and scored between 2/8 (Ahola et al. 2016; Stuij et al. 2017; Thomas et al. 2004) and 7/8 (Lloyd et al. 2010; Plotnikoff et al. 2006). Studies using qualitative design (Supplementary Table S3.5[1]) totalled 8 (Balfe et al. 2014; Dizon et al. 2019; Kennedy et al. 2018; Kilbride et al. 2011; Kime et al. 2018; Lascar et al. 2014; Martyn-Nemeth et al. 2019; Oser et al. 2019) and scored between 6/10 (Balfe et al. 2014; Kennedy et al. 2018; Kilbride et al. 2011; Lascar et al. 2014) and 8/10 (Kime et al. 2018; Martyn-Nemeth et al. 2019). Ranked lowest in the hierarchy were 8 text and opinion pieces (Supplementary Table S3.6[1]) (Colberg et al. 2015; Greener 2017; Kime and Pringle 2018, 2019; Narendran and Andrews 2018; National Institute for Health and Care Excellence 2018; Riddell et al. 2017a; Sundberg 2018) and a single narrative review (Klaprat et al. 2019).

Review findings

Like-items found within each concept (barriers and facilitators) were compiled into 13 groups (Table 2). The mind map (Fig. 2) conceptualises the distribution and nature of the literature while exposing synergies and inconsistencies between groups.

The following narrative refers to details of individual studies (see also Table 1 and Supplementary Table S5[1]).

Measures of PA

Of the 24 studies measuring PA, 6 used device-based measures of PA participation (Brazeau et al. 2014; Keshawarz et al. 2018; Martyn-Nemeth et al. 2017; McCarthy et al. 2017; Narendran et al. 2017; Scott et al. 2019); 2 studies utilised SenseWear Armbands (HealthWear Bodymedia, Pittsburgh, Pa., USA) (Brazeau et al. 2014;

Martyn-Nemeth et al. 2017), 2 used ActiGraph models (ActiGraph LLC, Pensacola, Fla., USA) (Keshawarz et al. 2018; Narendran et al. 2017), McCarthy et al. (2017) used the Yamax digi-walker pedometer (Yamasa Tokei Keiki Co. Ltd., Tokyo, Japan), and Scott et al. (2019) monitored heart rate remotely using the Polar Beat phone application (www.polar.com/beat/uk-en). All studies employing device-based PA measures collected data over a period of 1 to 2 weeks, with the exception of Scott et al. (2019), who monitored PA over the course of 6 weeks. Half (n = 12) used questionnaires, including the Godin Leisure-time Exercise Questionnaire (Plotnikoff et al. 2006, 2007, 2008, 2009, 2010a, 2010b), the Summary of Diabetes Self-care Activities Questionnaire (Kebede and Pischke 2019; Raaijmakers et al. 2015; Ruiz-González et al. 2016), the Scottish PA questionnaire (Hasler et al. 2000), the Kuopio Ischemic Heart Disease 12 month leisure time PA history (Ahola et al. 2012), and the International PA Questionnaire – long form (Duarte et al. 2012). The remaining 6 studies used researcher developed questionnaires or PA diaries (Ahola et al. 2016; Delmonte et al. 2013; Kneckt et al. 2001; Lloyd et al. 2010; Pinsker et al. 2016; Thomas et al. 2004). Two studies used a combination of both device-based and self-reported measures (McCarthy et al. 2017; Narendran et al. 2017).

Measures of barriers to PA

Fifteen studies measured barriers to PA for the purposes of describing perceived barriers. The most frequently used quantitative measure (n = 5) was the validated Barriers to PA in Diabetes – Type 1 (Dubé et al. 2006) (BAPAD1) tool (Brazeau et al. 2008, 2014; Dyck et al. 2018; Keshawarz et al. 2018; McCarthy et al. 2017). Other quantitative measures included the Diabetes Care Profile (Ruiz-González et al. 2016) and a researcher developed questionnaire (Stuij et al. 2017). Over half of the studies (n = 8) used qualitative methods to explore barriers to PA. These methods included focus groups (Martyn-Nemeth et al. 2019), one-on-one interviews (Balfe et al. 2014; Lascar et al. 2014), a combination of both focus groups and one-on-one interviews (Kennedy et al.2018; Kime et al. 2018), and open questions in researcher-developed questionnaires (Duarte

Fig. 1. Adapted Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram. BGL, blood glucose levels; T1D, type 1 diabetes. [Colour online.]
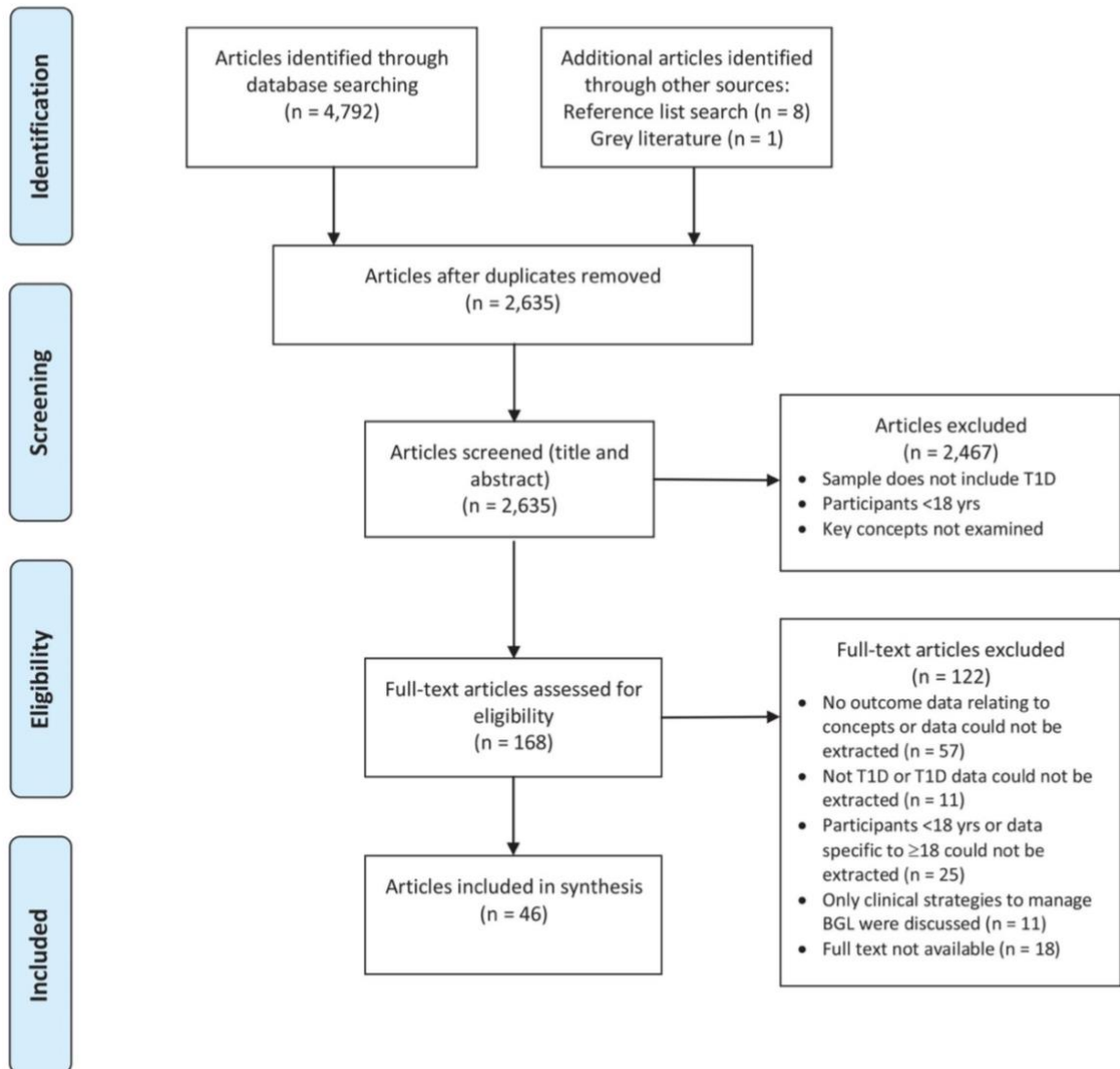
et al. 2012; Scott et al. 2019). One study used a combination of one-on-one interviews, participant journaling, and existing material on T1D blogs (Oser et al. 2019). Two studies using one-on-one interviews utilised a mixture of phone interviews as well as face-to-face interviews (Balfe et al. 2014; Kennedy et al. 2018).

Barriers

Of the 13 mapped barrier groups, *hypoglycaemia/fear of hypoglycaemia (FoH)* was detailed most frequently (*n* = 14) (Brazeau et al. 2008; Colberg et al. 2015; Duarte et al. 2012; Dyck et al. 2018; Greener 2017; Kennedy et al. 2018; Keshawarz et al. 2018; Kime et al. 2018; Martyn-Nemeth et al. 2019, 2017; McCarthy et al. 2017; Narendran and Andrews 2018; Oser et al. 2019; Scott et al. 2019), followed by

time/energy/motivation/work (*n* = 11) (Balfe et al. 2014; Brazeau et al. 2008; Duarte et al. 2012; Dyck et al. 2018; Kennedy et al. 2018; Kime et al. 2018; Lascar et al. 2014; Martyn-Nemeth et al. 2019; McCarthy et al. 2017; Oser et al. 2019; Scott et al. 2019). *Limited health professional support or advice* (Greener 2017; Kennedy et al. 2018; Kime and Pringle 2019; Narendran and Andrews 2018; Oser et al. 2019; Riddell et al. 2017; Stuij et al. 2017) and *psychosocial factors* (Duarte et al. 2012; Kennedy et al. 2018; Kime et al. 2018; Lascar et al. 2014; Lloyd et al. 2010; Narendran and Andrews 2018; Sundberg 2018) were the next most frequently reported barrier groups (each *n* = 7). The barriers reported least frequently (*n* = 1) were *hyperglycaemia* (Keshawarz et al. 2018) and *difficulties with activities of daily living (ADLs)* (Plotnikoff et al. 2007).

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Table 2. Concept group descriptions.

Concept groups	Item description
Barrier groups	
Time/energy/motivation/work	Time and energy involved in preparing for PA; lack of time; work; low motivation; general dislike of exercise
Environment	Difficulties accessing facilities; the burden of carrying supplies; weather or seasonality
Psychosocial factors	Embarrassment/discouragement to engage in PA by those around them; low confidence/overwhelmed by managing blood glucose levels for PA; diabetes distress; depression
Blood glucose level variability/ loss of control	Exercise inducing loss of control of diabetes or blood glucose levels.
Lack of knowledge	Lack of knowledge surrounding T1D management for PA
Hypoglycaemia/FoH	Fear of experiencing hypoglycaemia; actual episodes of hypoglycaemia
Limited HP support or advice	Limited HP support or advice available to those with T1D
Low fitness/tired	Low fitness levels; feeling tired or fatigued
Hyperglycaemia	Episodes of hyperglycaemia
Technology	Use of insulin pump; use of CGM
Demographic factors	Younger age; higher education; older age
Diagnosis of T1D	Being diagnosed/living with T1D
Difficulties with ADLs	Experiencing difficulties with ADLs
Facilitator groups	
Environment	Weather; access to facilities
Guidelines/increase patient knowledge	Availability of information and guidelines on insulin and nutrition adjustments and the effect of PA on blood glucose levels
Psychosocial factors	Sense of coherence; intention; self-esteem; self-efficacy; locus of control; self-motivation; stage of change (contemplators, preparers, maintainers); social/peer support; family support; enjoyment; well-being; perceived behavioural control
Positive biomarkers	$\dot{V}O_{2max}$; higher HDL; lower diastolic blood pressure
Less perceived disability/ADL difficulties	Lower level of perceived disability and less perceived difficulties with ADLs
Patient education	Structured education, workshops or courses – delivered in a group, one-on-one, or unspecified mode of delivery
Exercise programs	Programs, workshops or classes where exercise was performed by participants – delivered in a group, one-on-one, or unspecified mode of delivery
Technology	Activity tracking devices; insulin pumps; glucose monitors; continuous glucose monitors; artificial pancreas systems; social integration; phone applications
HP training and engagement	Need for HP training in the area of PA and T1D; HP to emphasise benefits of PA on T1D management; HP to engage with T1D patients and community sport; HP to encourage PA
Overcoming barriers/trial and error	Overcoming or addressing barriers to PA; trial and error of strategies to manage T1D with PA
Time management/goal setting	Improve time management; set goals
Reduce FoH	Address or reduce FoH
Demographic factors	Younger age (total and at diagnosis); full-time work; single; higher income

Note: ADL, activities of daily living; CGM, continuous glucose monitor; FoH, fear of hypoglycaemia; HDL, high-density lipoprotein; HP, health professional; PA, physical activity; T1D, type 1 diabetes; $\dot{V}O_{2max}$, maximal oxygen uptake.

Facilitators

The largest portion of articles investigating facilitators of PA participation fell within the *patient education* category (n = 15) (Brazeau et al. 2014; Dyck et al. 2018; Hasler et al. 2000; Kavookjian et al. 2007; Kennedy et al. 2018; Kime and Pringle 2018; Kime et al. 2018; Klaprat et al. 2019; Narendran and Andrews 2018; Narendran et al. 2017; Pillay et al. 2015; Plotnikoff et al. 2009; Riddell et al. 2017; Ruiz-González et al. 2016; Sundberg 2018). The next largest facilitator group was *psychosocial factors* with 14 articles in this group (Ahola et al. 2012; Balfe et al. 2014; Brazeau et al. 2008; Dizon et al. 2019; Hasler et al. 2000; Kilbride et al. 2011; Kime et al. 2018; Kneckt et al. 2001; Lascar et al. 2014; Narendran and Andrews 2018; Oser et al. 2019; Plotnikoff et al. 2008, 2010a, 2010b). *Health professional training and engagement* was reported on 8 occasions (Dizon et al. 2019; Kime and Pringle 2019; Kime et al. 2018; Narendran and Andrews 2018; National Institute for Health and Care Excellence 2018; Oser et al. 2019; Plotnikoff et al. 2009; Riddell et al. 2017a). *Positive biomarkers* (Keshawarz et al. 2018; Narendran et al. 2017), *less perceived disability/ ADL difficulties* (Plotnikoff et al. 2006, 2007), *reduce FoH* (Kilbride et al. 2011; Sundberg 2018), *and environment* (Balfe et al. 2014; Lascar et al. 2014) were the least reported facilitator groups. *Patient education*

and *exercise programs* were the only groups to include studies that trialled a facilitator. Five studies trialled *patient education* (Brazeau et al. 2014; Dyck et al. 2018; Hasler et al. 2000; Narendran et al. 2017; Ruiz-González et al. 2016) and 3 studies trialled *exercise programs* (Brazeau et al. 2014; Dyck et al. 2018; Scott et al. 2019). Two studies that trialled *exercise programs* also included *patient education* within the program (Brazeau et al. 2014; Dyck et al. 2018).

Discussion

This scoping review aimed to identify and map barriers and facilitators of PA in adults living with T1D. Forty-six articles published between 1996 and January 2020 were included in the scoping review. Research and opinion articles have steadily increased in this area over the last few years, with 21 of the included articles published between 2017 to 2019. Our review established that many of the included articles exhibited issues with methodological quality. Figure 2 (also see Table 2) identify pertinent barriers and facilitators of PA within the literature. The review supports the notion that "diabetes-specific" barriers, and in particular hypoglycaemia/ FoH, are the most commonly reported barriers to PA in this population. The review also reveals a disparity between what is known

Fig. 2. Mind map. The line and corresponding value joining *exercise programs* and *patient education* depicts the number of included articles that discussed both an exercise component and an educational component. [Colour online.]
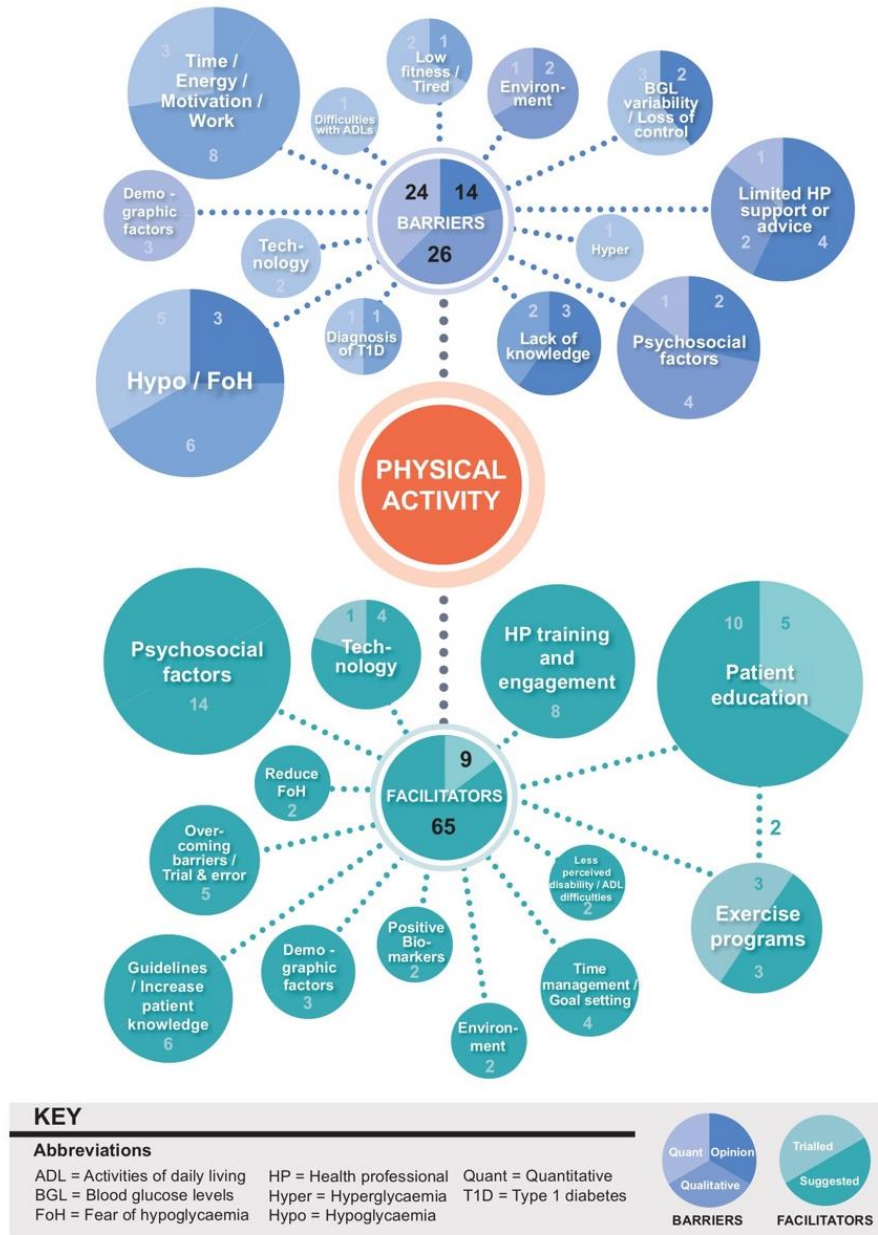
about barriers to PA and what is done to facilitate participation in PA. Although many facilitators have been suggested, very few have been trialled using robust study designs. The review does, however, identify some congruence within the literature. There is agreement that patient education should be provided to those living with T1D, psychosocial factors need to be addressed, and greater health professional knowledge and training is required in order for this

support to be given. Coordinated and meaningful interpretation of barriers and facilitators of PA is required to engage the T1D community and improve activity rates.

Fifteen articles discussed barriers to PA using quantitative methods, and the most popular tool was the BAPAD1 (Dubé et al. 2006). This tool is currently the only validated instrument specific to measuring barriers to PA in the T1D population. Using a

Likert scale (1, extremely unlikely; to 7, extremely likely), participants indicate the likelihood that each listed barrier (11 listed barriers) will keep them from exercising (Dubé et al. 2006). Although it does provide a platform for consistent and valid reporting of barriers, it may not capture or allow the researcher to understand the full breadth of issues experienced by this population. This might explain the large contribution of qualitative methods to explore barriers to PA.

Barriers identified in this review are a mix of diabetes-specific barriers and common barriers experienced by the general population. Of the 6 top ranking barriers to PA, 4 are diabetes specific: *hypoglycaemia/FoH*; *limited health professional support or advice*; *blood glucose level (BGL) variation/loss of control*, and *lack of knowledge*. The dominance of diabetes-specific barriers identified in this review is consistent with and explains lower activity rates in the T1D population. *Time/energy/motivation/work* was, however, the second most frequently reported barrier to PA. Time and lack of enjoyment are identified as the most salient barriers to PA in the general population (Australian Institute of Health and Welfare 2018; Hoare et al. 2017), so it is not surprising to see these barriers prominent in this review. The recommended management strategies for T1D and PA require meticulous planning (Riddell et al. 2017b); therefore, the additional tasks involved for the person living with T1D may accentuate *time, energy, and motivation* as a barrier. Seemingly "common" barriers may be experienced differently by those living with T1D and will need to be considered along with diabetes-specific barriers. General community PA initiatives will fall short of the needs of adults living with T1D, given their unique experience of barriers to PA. This population requires specifically tailored interventions before confidently participating in general community initiatives.

Given PA is a known precipitant of hypoglycaemia (Riddell et al. 2017b), it is conceivable that episodes of hypoglycaemia or a *fear* of hypoglycaemia is the most frequently described barrier to participating in PA (Brazeau et al. 2008; Colberg et al. 2015; Duarte et al. 2012; Dyck et al. 2018; Greener 2017; Kennedy et al. 2018; Keshawarz et al. 2018; Kime et al. 2018; Martyn-Nemeth et al. 2019; Martyn-Nemeth et al. 2017; McCarthy et al. 2017; Narendran and Andrews 2018; Oser et al. 2019; Scott et al. 2019). The experience of a hypoglycaemic episode, either lived or vicarious can be extremely unpleasant and may result in cessation of an activity or task (Frier 2008). Despite the clarity surrounding barriers to PA, only 2 articles *suggested* that addressing FoH may act as a facilitator to PA and no articles *trialled* an intervention explicitly targeting FoH (Kilbride et al. 2011; Sundberg 2018). The dominance of *hypoglycaemia/FoH* as a barrier should direct health professionals and future research to prioritise and understand hypoglycaemia/FoH when aiming to improve PA participation in adults living with T1D.

Upon scoping the literature for facilitators of PA, *patient education* emerged as a clear focus, followed by *psychosocial factors* and *health professional training and engagement*. The strong focus on *patient education* is consistent with *lack of knowledge* being among the most reported barriers to PA (Brazeau et al. 2014; Dyck et al. 2018; Hasler et al. 2000; Kavookjian et al. 2007; Kennedy et al. 2018; Kime and Pringle 2018; Kime et al. 2018; Klaprat et al. 2019; Narendran and Andrews 2018; Narendran et al. 2017; Pillay et al. 2015; Plotnikoff et al. 2009; Riddell et al. 2017a; Ruiz-González et al. 2016; Sundberg 2018). A modest number of articles also suggested *guidelines/increase patient knowledge* as a facilitator (Brazeau et al. 2008; Greener 2017; Kilbride et al. 2011; Kime et al. 2018; Lascar et al. 2014; National Institute for Health and Care Excellence 2018), which, along with *patient education*, may also address other, less obvious barriers. Knowledge and skills provided by patient education or guidelines may lead to confidence and competence in avoiding hypoglycaemia and BGL variation and may therefore work towards addressing the barriers of *BGL variation/loss of control* and *fear of hypoglycaemia/hypoglycaemia*. Despite their dominance, *patient*

education and *guidelines/increase patient knowledge* were predominately *suggested* (as opposed to *trialled*) as facilitators. This review found that many possible facilitators were *suggested* at the conclusion of articles as a way to address issues identified in the article. Very few proceeded to *trial* the feasibility or efficacy of these possible facilitators (Brazeau et al. 2014; Dyck et al. 2018; Hasler et al. 2000; Narendran et al. 2017; Ruiz-González et al. 2016). General diabetes self-management education is already recommended by diabetes authorities for people living with T1D (Craig et al. 2011; National Institute for Health and Care Excellence 2018), so it is plausible to see authors suggesting *patient education* as a facilitator of PA (Kavookjian et al. 2007; Kennedy et al. 2018; Kime and Pringle 2018; Kime et al. 2018; Klaprat et al. 2019; Narendran and Andrews 2018; Pillay et al. 2015; Plotnikoff et al. 2009; Riddell et al. 2017a; Sundberg 2018). It is widely accepted, however, that behaviour change, including increasing PA, requires more than just knowledge and skill, the hallmarks of patient education (Knight et al. 2006). This is particularly true for those living with T1D who may be exposed to diabetes-specific burden and diabetes distress, further complicating behaviour change efforts (Knight et al. 2006; Speight et al. 2011). Behaviour change theories that propose psychosocial concepts such as self-efficacy and self-determined motivation need to be embedded within education programs to facilitate behaviour change (Knight et al. 2006; Ntoumanis et al. 2020).

Of the 5 trialled *patient education* facilitators, only 3 were trialled with interventions based on behaviour change theories (Brazeau et al. 2014; Hasler et al. 2000; Narendran et al. 2017), which is a finding consistent with general diabetes education interventions (Knight et al. 2006). Behaviour change theories can describe how, when, and why change occurs or does not occur and are crucial in developing effective behaviour change interventions (Michie and Johnston 2012). Having a theoretical basis to an intervention has been shown to improve efficacy and is emphasised in key frameworks for developing behaviour change interventions (Craig et al. 2008; Dombrowski et al. 2012; Taylor et al. 2012). The 3 studies to trial theory-driven behaviour change interventions were all pilot RCTs. The theories described were the Transtheoretical Model (Hasler et al. 2000), Goal Orientated Motivational Interviewing (Narendran et al. 2017), Theory of Planned Behaviour (Brazeau et al. 2014), and Social Cognitive Theory (Brazeau et al. 2014). Furthermore, none of the included studies reported the use of any behaviour change techniques. Consistent reporting of behaviour change techniques or the "active ingredients" of interventions is essential for fidelity, replication, and synthesis of interventions (Michie and Johnston 2012; Teixeira et al. 2020).

In order to develop effective *patient education*, training of health professionals and improving their engagement with the T1D community is essential. *Health professional training and engagement* was suggested as a (potential) facilitator to PA on 8 occasions (Dizon et al. 2019; Kime and Pringle 2019; Kime et al. 2018; Narendran and Andrews 2018; National Institute for Health and Care Excellence 2018; Oser et al. 2019; Plotnikoff et al. 2009; Riddell et al. 2017a), making it the third most discussed facilitator. This echoes the literature exploring barriers to PA, where *limited health professional support or advice* was the third most commonly reported barrier to PA. The review demonstrates agreement in the literature among experts and people living with T1D that health professionals do not possess adequate knowledge or confidence to assist people living with T1D in the area of PA (Dizon et al. 2019; Greener 2017; Kennedy et al. 2018; Kime and Pringle 2019; Kime et al. 2018; Narendran and Andrews 2018; National Institute for Health and Care Excellence 2018; Oser et al. 2019; Plotnikoff et al. 2009; Riddell et al. 2017a; Stuij et al. 2017). Although a prominent *suggested* facilitator, this review has revealed no formal examination or discussion of an effective way to improve *health professional training and engagement*.

Psychosocial factors were prominent as both a barrier and suggested facilitator of PA. It is logical to expect negative psychosocial factors to act as barriers (e.g., diabetes distress, depression, embarrassment, low confidence) and positive psychosocial factors as facilitators (e.g., greater social support, well-being, enjoyment, self-efficacy, self-esteem, motivation) (Table 2). Among psychosocial facilitators, social support was suggested most frequently (*n* = 7), a finding that juxtaposes with the most frequently reported psychosocial barriers: low confidence/overwhelmed and embarrassment/discouragement (each *n* = 3) (Balfe et al. 2014; Brazeau et al. 2008; Dizon et al. 2019; Duarte et al. 2012; Kennedy et al. 2018; Kime et al. 2018; Lascar et al. 2014; Narendran and Andrews 2018; Oser et al. 2019; Sundberg 2018). Self-efficacy (a predictor of PA behaviour change) and social support are highly correlated (McAuley et al. 2003). Using social support in intervention design may improve self-efficacy, enjoyment, and motivation towards PA, hence increasing the likelihood of PA behaviour change (Ntoumanis et al. 2018*b*; Plotnikoff et al. 2008). Although theoretically sound, these strategies are yet to be explored beyond small pilot studies in the area of PA and T1D (Brazeau et al. 2014; Dyck et al. 2018).

Gap in the literature

Technology in T1D management is developing rapidly and becoming more accessible (Atkinson et al. 2014), yet it did not feature heavily in this review. Devices such as insulin pumps, continuous glucose monitoring (CGM), T1D, and activity-specific phone applications as well as closed-loop systems (artificial pancreas or automated insulin delivery) are already having a dramatic impact on general T1D management (Atkinson et al. 2014). It is surprising we only found 2 barriers related to access/use of technology and only 5 facilitators linked to technology, many of which were from the same opinion piece (Colberg et al. 2015; Dizon et al. 2019; Kebede and Pischke 2019; Keshawarz et al. 2018; Pinsker et al. 2016; Scott et al. 2019). Adding to the ambiguity in this area, insulin pumps and CGM were identified as both barriers and facilitators of PA (Colberg et al. 2015; Dizon et al. 2019; Keshawarz et al. 2018; Pinsker et al. 2016). In the opinion of health professionals and athletes with T1D, insulin pumps and CGM may facilitate PA (Colberg et al. 2015; Dizon et al. 2019). However, 2 articles found that those using CGM and or insulin pumps experienced more barriers to PA and/or participated in less activity than those not using this technology (Keshawarz et al. 2018; Pinsker et al. 2016). Articles were excluded if PA participation was not an outcome of the study, as such, a number of articles exploring efficacy of using technology in relation to glycaemic control were excluded. The low quality and small number of articles examining technology as either a barrier or facilitator indicates a need for further research to examine the role of technology in overcoming barriers and increasing participation in PA.

Technology should also be a consideration in the design of future studies where PA participation is an outcome. Despite their availability, the use of PA tracking devices was extremely limited. Only 5 studies utilised accelerometry to measure PA (Brazeau et al. 2014; Keshawarz et al. 2018; Martyn-Nemeth et al. 2017; McCarthy et al. 2017; Narendran et al. 2017), while others relied on validated and nonvalidated questionnaires. Self-reported PA levels obtained via questionnaires are known to be subject to bias and over-reporting of activity (Kapteyn et al. 2018).

Limitations

Although an optional component of a scoping review (Tricco et al. 2018), we included critical appraisal of the reviewed studies. Given the type and aim of the review, a minimum-quality threshold was not enforced and all articles were included. In doing so, we discovered substantial variation in methodological rigour (Supplementary Tables S3.1 to S3.6[1]). The small number of rigorous studies in the area explains why there were no recent systematic reviews solely focussed on barriers and/or facilitators of PA participation in the T1D population. Only 3 review articles were identified, one of which was a narrative review with substantial methodological issues (Klaprat et al. 2019). The average sample size (*n* = 34) of the 6 experimental studies included in this review was very low (Brazeau et al. 2014; Dyck et al. 2018; Hasler et al. 2000; Narendran et al. 2017; Ruiz-González et al. 2016; Scott et al. 2019). The 3 included RCTs were all pilot studies, also of varying quality (Brazeau et al. 2014; Hasler et al. 2000; Narendran et al. 2017). The remaining 3 experimental studies were of quasi-experimental design (Dyck et al. 2018; Ruiz-González et al. 2016; Scott et al. 2019), leaving the bulk of the included articles in the lower half of the evidence hierarchy (JBI 2017).

Conclusions

The available literature examining barriers and facilitators of PA participation for people with T1D is limited and is dominated by articles possessing methodological concerns. Evidence relating to issues influencing participation in PA in this population is growing, pointing to diabetes-specific barriers as the prominent concerns for people living with T1D. *Patient education* was the most commonly suggested or trialled facilitator of PA. The dominance of *patient education* as a suggested and trialled facilitator addresses diabetes-specific barriers to PA, while *psychosocial factors* as both barriers and facilitators need to be considered in future intervention designs. The need for greater *health professional support and advice* has been met with frequent suggestions that this factor is likely to facilitate PA in this population. Major inconsistencies in the literature were also established. The most frequently identified barrier, *hypoglycaemia/FoH* was rarely explicitly targeted when exploring facilitators to PA. A major limitation of the research to date is the extremely small number of studies trialling behaviour change interventions in this area. Despite a considerable number of suggested facilitators, very few studies trialled interventions to increase PA. Of those that did, the majority were pilot studies trialling group or one-on-one interventions. Finally, the role of technology in overcoming barriers and increasing participation in PA was considerably underrepresented in this review, given the large role it plays in daily management of T1D. The current state of evidence is insufficient to confidently inform future practice among diabetes health professionals.

Fully powered randomised controlled trials are required to establish efficacy of behaviour change interventions targeting hypoglycaemia/FoH and other psychosocial factors. Researchers are called to consider device-based measures of PA and complement quantitative findings with qualitative assessment of acceptability. These trials should include interventions based on sound theoretical foundations, using and reporting appropriate behaviour change techniques.

In addition to developing behaviour change interventions for those living with T1D, systematically designed and evaluated training programs for health professionals are needed in the area of T1D and PA. Researchers should strive for better dissemination to health professionals of the latest evidence-based approaches to T1D management for PA. Consistent and reputable information communicated by health professionals, using motivationally supportive language is an important part of improving activity levels in this population (Ntoumanis et al. 2018*a*).

Continued exploration of barriers to PA is required within local T1D communities. Using a quantitative measure of barriers to PA, such as the BAPAD1 tool (Dubé et al. 2006), is useful in synthesising evidence in this area. However, in an era of rapidly evolving management strategies and devices, barriers to PA may change, thus continued exploration of the problems faced by local T1D communities will be important. To provide future balanced and insightful representation of the barriers faced by the T1D population, a mixed method approach is recommended; this might

include using a validated quantitative tool such as the BAPAD1, together with qualitative focus group interviews.

Conflict of interest statement

M.C.B. is an employee of Diabetes Western Australia; however, the organisation had no influence on the conceptualisation, operationalisation, or conclusions of this review. J.A.B., N.N., and G.D.L. declare no conflicts of interest.

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Appendix A Publication Appendix

The following appendix includes supplements to the publication presented above. Online versions are also available at https://doi.org/10.1139/apnm-2020-046.

Supplementary Table S1

PRISMA-ScR Checklist

Section	Item	PRISMA-ScR Checklist item	Reported on Page #
Title			
Title	1	Identify the report as a scoping review.	1
Abstract			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	2
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	5-6
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	6-7
Methods			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	6
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	8-9
Information sources	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	8-9
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Supp 2
Selection of sources of evidence	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	8-9

Section	Item	PRISMA-ScR Checklist item	Reported on Page #
Data charting process	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	10-11
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	p. 10 Supp 4
Critical appraisal of individual sources of evidence	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	9-10
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	10-11
Results			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	11 Fig 1.
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	11 Table 1
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	12-13 Supp 3
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	13-17 Supp 5
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	13-17 Figure 2
Discussion			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	17-23
Limitations	20	Discuss the limitations of the scoping review process.	23
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	25-26
Funding			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	27

Supplementary Table S2

Sample Search Strategy – CINAHL full text (EBSCO)

Search	Query	Records retrieved
S1	(MH "Diabetes Mellitus, Type 1")	22,426
S2	(MH "Physical Fitness+") OR (MH "Sports+") OR (MH "Leisure Activities+") OR (MH "Exercise+") OR (MH "Physical Activity")	226,538
S3	(MH "Health Education") OR (MH "Diabetes Education") OR (MH "Learning Methods+") OR "client education" OR "education" OR "health promotion" OR "structured education" OR "group education" OR "group program" OR "group intervention" OR "program*" OR "counsel#ing" OR "strateg*" OR "facilitators" OR "method" OR "motivators" OR "enablers" OR "barriers to PA" OR "barriers" OR "problems" OR "challenges" OR "issue*" OR "difficult*" OR "compliance" OR "non#compliance" OR "associations" OR "correlations" OR "links" OR "predictors"	1,985,495
S4	S1 AND S2 AND S3	416
Limiters - Published date: 01/01/1996 – 03/02/2020; English language; Human		186

Note. Search conducted on 3rd February 2020

Supplemental Tables S3.1-3.6

Critical Appraisal

Table S3.1

Systematic Review and Research Synthesis

Citation	Q1 **Is the review question clearly and explicitly stated?** It was agreed that a clearly and explicitly stated review question would be formulated around PICO elements	Q2 **Were the inclusion criteria appropriate for the review question?** It was agreed that if inclusion criteria were adequately described, even in the absence of a PICO statement, this criterion would be met	Q3 **Was the search strategy appropriate?** It was agreed that if a search strategy was not explicitly detailed, *uncertain* would be assigned	Q4 **Were the sources and resources used to search for studies adequate?** It was agreed that if a search strategy was not explicitly detailed, *uncertain* would be assigned	Q5 **Were the criteria for appraising studies appropriate?** It was agreed that if critical appraisal was not explicitly detailed, this criterion was not met	Q6 **Was critical appraisal conducted by two or more reviewers independently?** It was agreed that if critical appraisal processes were not explicitly detailed, *uncertain* would be assigned	Q7 **Were there methods to minimize errors in data extraction?** It was agreed that if specific tools to guide data extraction were not used, this criterion would not be met	Q8 **Were the methods used to combine studies appropriate?** It was agreed that in order to meet this criterion, the synthesis must be appropriate for the review question and the stated type of review	Q9 **Was the likelihood of publication bias assessed?** It was agreed that if the search strategy was not comprehensive and or statistical tests to assess bias were not used, this criterion would not be met	Q10 **Were recommendations for policy and/or practice supported by the reported data?** It was agreed that if there was evidence the strength and quality of the findings were considered in formulating recommendations, this criterion would be met	Q11 **Were the specific directives for new research appropriate?** It was agreed that if the review considered and reported gaps in research or knowledge base, this criterion would be met	Score
Kavookjian et al. (2007)	Y	Y	Y	Y	Y	Y	N	N	N	Y	Y	8/11

Klaprat et al. (2019)*	N	Y	U	U	N	U	U	U	N	Y	Y	3/11
Pillay et al. (2015)	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10/11
%	33.33	100.0	66.66	66.66	66.66	66.66	33.33	33.33	33.33	100.0	100.0	

Note. *This narrative review is positioned here to align with the JBI instrument used to critically appraise it and is not reflective of its position in the evidence hierarchy

Table S3.2

Randomised Controlled Trials

Citation	**Q1** Was true randomisation used for assignment of participants to treatment groups? It was agreed that if a detailed description of the randomisation procedure was not provided, *unclear* would be assigned	**Q2** Was allocation to treatment groups concealed? It was agreed that concealment of allocation referred to the personnel allocating participants into groups	**Q3** Were treatment groups similar at the baseline? It was agreed that if participant characteristics (particularly those that may explain the effect in the absence of the cause) were not similar, this criterion would not be met	**Q4** Were participants blind to treatment assignment? It was agreed that if not explicitly described, *unclear* would be assigned	**Q5** Were those delivering treatment blind to treatment assignment?	**Q6** Were outcomes assessors blind to treatment assignment?	**Q7** Were treatment groups treated identically other than the intervention of interest?	**Q8** Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed? It was agreed that incomplete follow up was defined as incomplete information on all participants	**Q9** Were participants analysed in the groups to which they were randomised? It was agreed that this item was related to intention to treat analysis	**Q10** Were outcomes measured in the same way for treatment groups?	**Q11** Were outcomes measured in a reliable way? It was agreed that if a valid and reliable measure existed and was available but not used, this criterion was not met	**Q12** Was appropriate statistical analysis used?	**Q13** Was the trial design appropriate, and any deviations from the standard RCT design accounted for in the conduct and analysis of the trial?	Score
Brazeau et al. (2014)	Y	Y	Y	N	N	U	Y	Y	Y	Y	Y	N	Y	9/13
Hasler et al. (2000)	U	U	U	U	N	U	U	U	U	Y	Y	N	Y	3/13

Narendran et al. (2017)	Y	Y	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	9/13
%	66.66	66.66	33.33	0.0	0.0	0.0	66.66	66.66	66.66	100.0	100.0	66.66	100.0	

Table S3.3

Quasi-Experimental Studies

Citation	Q1 Is it clear in the study what is the 'cause' and what is the 'effect'? It was agreed that if the *cause* (independent variable) did not occur before the *effect* (dependent variable), this criterion would not be met	Q2 Were the participants included in any comparisons similar? It was agreed that if there was no comparison, this criterion was deemed *not applicable* (N/A)	Q3 Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest? It was agreed that if there was no comparison, this criterion was deemed *not applicable* (N/A)	Q4 Was there a control group? It was agreed that to satisfy this criterion, the control group should be an independent, separate control group, not pre-test group in a pre-post-test design	Q5 Were there multiple measurements of the outcome both pre and post the intervention/exposure? It was agreed that if there were multiple post-test measurements of the outcome, this criterion would be met	Q6 Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed? It was agreed that incomplete follow up was defined as incomplete information on all participants	Q7 Were the outcomes of participants included in any comparisons measured in the same way? It was agreed that if there was no comparison, this criterion would be deemed *not applicable* (N/A)	Q8 Were outcomes measured in a reliable way? It was agreed that if a valid and reliable measure existed and was available but not used, this criterion would not met	Q9 Was appropriate statistical analysis used?	Score
Dyck et al. (2018)	Y	N/A	N/A	N	N	N	N/A	Y	Y	3/6
Ruiz-Gonzalez et al. (2016)	Y	Y	Y	N	Y	N	Y	Y	Y	7/9
Scott et al. (2019)	Y	N/A	N/A	N	N	U	N/A	Y	Y	3/6
%	100.0	33.33	33.33	0.0	33.33	0.0	33.33	100.0	100	

Table S3.4

Analytical Cross-Sectional Studies

Citation	**Q1** Were the criteria for inclusion in the sample clearly defined? It was agreed that if these details were described in earlier referenced, studies, this criterion was met	**Q2** Were the study subjects and the setting described in detail? It was agreed that if these details were described in earlier referenced, studies, this criterion was met	**Q3** Was the exposure measured in a valid and reliable way? It was agreed that if a valid and reliable measure existed and was available but not used, this criterion was not met	**Q4** Were objective, standard criteria used for measurement of the condition? It was agreed patient-report does not constitute objective, standard criteria	**Q5** Were confounding factors identified? It was agreed that this may have occurred in study design, data analysis or limitations section of the study	**Q6** Were strategies to deal with confounding factors stated? It was agreed that if there were no identified confounding factors, this criterion would be marked not applicable (N/A)	**Q7** Were the outcomes measured in a valid and reliable way? It was agreed that if a valid and reliable measure existed and was available but not used, this criterion was not met	**Q8** Was appropriate statistical analysis used?	Score
Ahola et al. (2012)	U	U	Y	Y	Y	Y	Y	Y	6/8
Ahola et al. (2016)	U	U	N	Y	N	N	N	Y	2/8
Brazeau et al. (2008)	N	Y	Y	Y	N	N	Y	Y	5/8
Delmonte et al. (2013)	Y	Y	Y	Y	N	N/A	U	Y	5/7
Duarte et al. (2012)	Y	Y	Y	Y	N	N	N	Y	5/8
Kebede and Pischke (2019)	N	Y	Y	U	Y	Y	Y	Y	6/8
Keshawarz et al. (2018)	N	N	Y	U	Y	Y	Y	Y	5/8

Kneckt et al. (2001)	Y	Y	Y	Y	N	N	Y	Y	6/8
Lloyd et al. (2010)	Y	Y	Y	Y	Y	Y	U	Y	7/8
Martyn-Nemeth et al. (2017)	Y	Y	Y	U	U	N	Y	Y	5/8
McCarthy et al. (2017)	Y	Y	Y	Y	U	U	Y	Y	6/8
Pinsker et al. (2016)	Y	Y	U	N	U	N	U	Y	3/8
ALEXANDRA Study - Plotnikoff et al. (2010)	Y	Y	Y	Y	N	N/A	Y	Y	6/7
ALEXANDRA Study – Plotnikoff et al. (2009)	Y	Y	Y	Y	N	N/A	Y	Y	6/7
ALEXANDRA Study – Plotnikoff et al. (2007)	Y	Y	U	Y	N	N/A	Y	Y	5/7
ALEXANDRA Study – Plotnikoff et al. (2010)	Y	Y	Y	Y	N	N/A	Y	Y	6/7
ALEXANDRA Study – Plotnikoff et al. (2006)	Y	Y	Y	Y	U	Y	Y	Y	7/8
ALEXANDRA Study – Plotnikoff et al. (2008)	Y	Y	Y	Y	N	N/A	Y	Y	6/7

Raaijmakers et al. (2015)	N	Y	Y	U	Y	Y	Y	Y	6/8
Stuij et al. (2017)	N	Y	U	U	U	U	N	Y	2/8
Thomas et al. (2004)	N	Y	U	N	N	N	N	Y	2/8
%	61.9	85.71	76.19	66.66	23.8	28.57	66.66	100.0	

Table S3.5

Qualitative Research

Citation	Q1 Is there congruity between the stated philosophical perspective and the research methodology? It was agreed that if a specific philosophical perspective was not stated, evidence of a sound qualitative approach would satisfy this criterion	Q2 Is there congruity between the research methodology and the research question or objectives? It was agreed that if the study design was congruent with the interpretive paradigm this criterion was met	Q3 Is there congruity between the research methodology and the methods used to collect data? It was agreed that if the study methods were congruent with the interpretive paradigm, this criterion was met	Q4 Is there congruity between the research methodology and the representation and analysis of data? It was agreed that if the representation and analysis of data were congruent with the interpretive paradigm, this criterion was met	Q5 Is there congruity between the research methodology and the interpretation of results? It was agreed that if the interpretation of results were congruent with the interpretive paradigm, this criterion was met	Q6 Is there a statement locating the researcher culturally or theoretically? It was agreed that statements relating to the influence of the researcher's beliefs or values would satisfy this criterion	Q7 Is the influence of the researcher on the research, and vice-versa, addressed? It was agreed that any attempt at describing this relationship would satisfy this criterion	Q8 Are participants, and their voices, adequately represented? It was agreed that inclusion of participant quotes would satisfy this criterion	Q9 Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?	Q10 Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data? It was agreed that this criterion was met if the conclusions drawn were based on the data collected	Score
Balfe et al. (2014)	U	Y	Y	Y	U	N	N	Y	Y	Y	6/10
Dizon et al. (2019)	Y	Y	Y	Y	Y	N	N	Y	Y	Y	8/10
Kennedy et al. (2018)	U	Y	Y	Y	U	N	N	Y	Y	Y	6/10
Kilbride et al. (2011)	U	Y	N	Y	Y	N	N	Y	Y	Y	6/10

Kime et al. (2018)	Y	Y	Y	Y	Y	N	N	Y	Y	Y	8/10
Lascar et al. (2014)	U	Y	Y	Y	U	N	N	Y	Y	Y	6/10
Martyn-Nemeth et al. (2019)	Y	Y	Y	Y	Y	N	N	Y	Y	Y	8/10
Oser et al. (2019)	U	Y	Y	Y	Y	N	N	Y	Y	Y	7/10
%	37.5	100.0	87.5	100.0	62.5	0.0	0.0	100.0	100.0	100.0	

Table S3.6

Text and Opinion Articles

Citation	Q1 Is the source of the opinion clearly identified? It was agreed if there was a named author, this criterion was met	Q2 Does the source of opinion have standing in the field of expertise? It was agreed that authors without diabetes related qualifications, appointments or affiliations did not satisfy this criterion	Q3 Are the interests of the relevant population the central focus of the opinion? It was agreed that if the author's purpose of writing the article did not align with the intended audience, this criterion was not met	Q4 Is the stated position the result of an analytical process, and is there logic in the opinion expressed? It was agreed that if the main points of the article have not been argued, supported and presented in a logical way, this criterion was not met	Q5 Is there reference to the extant literature? It was agreed that if extant literature was referenced with bias or was inconclusive, this criterion was not met	Q6 Is any incongruence with the literature/sources logically defended? It was agreed that if the article did not explicitly express an opinion, *not applicable* (N/A) was assigned	Score
Colberg et al. (2015)	Y	Y	Y	Y	Y	N/A	5/5
Greener (2017)	Y	N	Y	Y	Y	Y	5/6
Kime and Pringle (2018)	Y	Y	Y	N	Y	Y	5/6
Kime and Pringle (2019)	Y	Y	Y	Y	N	N	4/6
Narendran and Andrews (2018)	Y	Y	Y	Y	Y	Y	6/6
National Institute for Health and Care Excellence (2018)	Y	Y	Y	Y	Y	N/A	5/5

M. C. Riddell et al. (2017)	Y	Y	Y	Y	Y	Y	6/6
Sundberg (2018)	Y	Y	Y	Y	Y	N/A	5/5
%	100.0	87.5	100.0	87.5	75.0	50.0	

Supplementary Table S4

Data Extraction Tool

Scoping review details	
Scoping Review title:	
Review objective/s:	
Review question/s:	
Inclusion/exclusion criteria	
Population	
Concept	
Context	
Types of Study	
Article details and characteristics	
Article citation details (e.g., author/s, date, title, journal, volume, issue, pages)	
Article/review type	
Country	
Context	
Participants (details e.g., age/sex and number)	
Details/results extracted from article (in relation to the concept of the scoping review)	
Aim / Hypothesis / Objectives	
Recruitment methods (or search strategy for reviews)	
Barriers to physical activity participation	
Tools used to measure barriers	

Associations or correlations (with physical activity / barriers to physical activity)	
Measure of physical activity participation	
Facilitator of physical activity	
Key Findings	

Note. Adapted from JBI data extraction instrument (Peters et al., 2020)

Supplementary Table S5

Individual Sources of Evidence

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
Kavookjian et al. (2007)	To assess and summarise evidence and gaps in the literature regarding the intervention for being active among individuals with diabetes	Systematic review	T1D Adults	Included interventions involved any type of PA, individual or group, delivered via didactic communication or collaborative effort and using written, computer-based, or visual materials	More research required to determine if exercise consultation results in sustained PA Very little research exists on learning/behavioural outcomes or on clinical outcomes
Klaprat et al. (2019)	An updated overview of: What we know about PA for persons with T1D Gaps in the literature that could guide future research programs Explore the benefits of patient engagement and co-development of a research agenda	Narrative review	T1D Adults	Behavioural trials that motivate individuals to adopt a more active lifestyle	Lack of adequately powered clinical trials of PA on health-relate outcomes Lack of optimal theoretical model for long term adherence to PA Lack of optimal delivery model for increasing PA
Pillay et al. (2015)	To determine the effects of behavioural programs for patients with T1D on behavioural, clinical, and health outcomes and to investigate factors that might moderate effect	Systematic review	T1D Adults Mean age ranged from: 30 - 49 yrs Mean HbA1c ranged from: 7.7% - 9.6%	Behavioural programs	Insufficient evidence to suggest behavioural programs significantly change PA (intensity/duration) when compared to usual care

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
Brazeau et al. (2014)	To examine the efficacy of a physical exercise promotion program to improve total energy expenditure in adults with T1D	RCT	T1D Adults Mean age: Intervention: 45.1 ±14.5 yrs Control: 44.2 ±12.5 yrs Mean duration of diabetes: Intervention: 20.3 ±12.9 yrs Control: 24.4 ±13.6 yrs	Group program of PA promotion and exercise activities / Information leaflet	No significant improvement to TEE or PAL. 14% improvement of VO2peak in intervention group from baseline to 3 months: Baseline: 24.6 (22.0-27.2) ml/kg/min 3 months: 28.2 (24.9-31.3) ml/kg/min ($p = 0.003$)
Hasler et al. (2000)	To evaluate the effectiveness of 1:1 exercise consultation in increasing PALs	RCT	T1D Adults Mean age: 33.1 ±9.2 yrs	Exercise consultation (1:1) / Information leaflet	64.8% increase in LTPA in intervention pre to post (3 weeks) ($p = 0.045$). No significant change in control Intervention participants identified as 'contemplators' or 'preparers' at baseline associated with higher percentage participating in sport and exercise after intervention Intervention participants identified as 'maintainers' at baseline associated with higher percentage participating in overall LTPA after intervention
Narendran et al. (2017)	A pilot trial to address the key uncertainties in designing a definitive trial to test whether exercise preserves beta-cell function	RCT	T1D Adults Mean age: 32.3 ±10.5 yrs Mean duration of diabetes: 12 ±27	Exercise training (goal-oriented motivational interviewing, graded unsupervised exercise program, PA log) plus usual care / Usual care alone	Participants meeting 150 min/week moderate intensity PA (self-reported) increased from 16% to 61% in intervention compared to 21% to 12% in control (baseline – 6 months) Intervention increased from 243 ±141 min

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
			months Mean HbA1c: 9 ±2.3%		MVPA/wk to 285 ±40 min/wk at 6 months and 273 ±34 min/wk at 12 months. Control decreased MVPA/wk at 6 months MVPA/wk correlated with VO2max
Dyck et al. (2018)	To use education sessions and exercise classes to improve exercise self-efficacy in individuals with T1D	Quasi-experimental	T1D Adults Mean age: 44.1 yrs Duration of diabetes: >1 year HbA1c: <10%	4 boot camp sessions (once per week) Each weekly session: 30-minute education session + group exercise class / No control	Barriers to PA (BAPAD1): "Loss of control over diabetes" – rated highest (3.00 ±2.04) "Your work/school schedule" (2.83 ±1.77) "Fear of being tired" (2.42 ±1.85) "Risk of hypoglycaemia" (2.25 ±1.69) Positive correlation between number of hypoglycaemic events and BAPAD1 scores (r = 0.82, p = 0.001) No significant change to BAPAD1 score pre-post
Ruiz-Gonzalez et al. (2016)	To implement an intensive and practical diabetes education program and evaluate long-term effects and impact on psychosocial variables	Quasi-experimental	T1D Adults Mean age: 32.8 ±14.16 yrs	Educational program (group) – 3 sessions delivered by a diabetes educator / Participants are their own controls	Self-care barriers including exercise significantly decreased after the educational program (p < 0.01) Pre = 2.56 ±1.71 6 months post = 1.92 ±1.49 1year 2.15 ±1.36 (All scores out of 10) No significant change to frequency of physical exercise.
Scott et al. (2019)	To evaluate virtually monitored home-based high intensity	Quasi-experimental	T1D Adults	Six-week virtually monitored Home-HIT program / No control	95% adherence to unsupervised Home-HIT

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
	interval training (Home-HIT) in people with T1D		Mean age: 30 ±3 yrs Mean duration of diabetes: 10 ±2 yrs Mean HbA1c: 8 ±0.6%		Home-HIT increased VO_{2peak} by 7% (p=0.017) Positives about HOME-HIT: Convenience Time efficiency More stable BGLs Virtual monitoring improved motivation Use of remotely monitored heart rate suggested to improve uptake, adherence, compliance to exercise Top three barriers to Home-HIT: Lack of time (91%) FoH (27%) Lack of motivation (18%)
Ahola et al. (2012)	To study the associations between sense of coherence and self-care practices in patients with T1D	Cross-sectional	T1D Adults Median age: 44 (35-53) yrs Median duration of diabetes: 27.2 (17.3-37.1)	N/A	Sense of coherence scores correlated with observed weekly LTPA (MET hours) r = 0.098 p = 0.004 Sense of coherence score predicted MET hour values in men but not women

Author	Aims	Design	Population/participants	Intervention / control	Key findings
Ahola et al. (2016)	To study the association between FoH and various diabetes self-management practices	Cross-sectional	T1D Adults with FoH Mean age: Women: 47.2 ±13.6 yrs Men: 48.6 ±13.3 yrs Mean duration of diabetes: Women: 31.2 ±13.3 yrs Men: 30.8 ±14.1 yrs	N/A	No differences observed in levels of reported PA by FoH status. Median MET hours/number of journal days: Men FoH: 4.3 (2.5-8.4) No FoH: 5 (2.4-8.6) $p = 0.901$ Women FoH: 5.3 (3.2-8.3) No FoH: 4.5 (2.7-8) $p = 0.242$
Brazeau et al. (2008)	To determine, in an adult population with T1D, barriers to regular PA using a 'diabetes-specific' barriers measure and factors associated with these barriers	Cross-sectional	T1D Adults Mean age: 43.5 ±11.6 yrs Mean duration of diabetes: 23.3 ±13.2 yrs Mean HbA1c: 7.7 ±1.1%	N/A	Barriers to PA (BAPAD1): FoH 3.58 ±2.02 Work schedule 3.05 ±1.98 Loss of control over diabetes 2.83 ±1.80 Low levels of fitness 2.83 ±1.95 Correlates of barriers: Perceived well-being, knowledge of insulin pharmacokinetics, implementation of strategies to reduce the probability of exercise-induced hypoglycaemia, greater social support and having someone to perform PA with were associated with fewer barriers.
Delmont et al. (2013)	To investigate how islet transplantation influenced diet, exercise habits, and body	Cross-sectional	T1D Adults who have undergone islet transplant	Islet transplant / No control	No significant change in average hours/week of voluntary PA during the 10-year follow-up (average 5.3 ±5.6 hours/wk)

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
	composition during 10 years after transplantation		Mean age: 45.8 ±8 yrs Mean duration of diabetes: 37 ±11 yrs		
Duarte et al. (2012)	To compare PAL and care related to exercise in patients with diabetes mellitus	Cross-sectional	T1D Adults Mean age: 37 ±11 yrs Mean duration of diabetes: 17 ±9 yrs Mean HbA1c: 9.2 ±2.2%	N/A	Reasons for not exercising: Lack of time 43.9% Discouragement 17.5% Patient does not like exercise 8.8% Hypoglycaemia 8.8% ($p<0.001$)
Kebede and Pischke (2019)	To investigate the association of diabetes app use and other factors with self-care behaviour (including PA)	Cross-sectional	T1D Adults Mean age: 39 ±12.9 yrs	N/A	Using a diabetes app associated with greater PA (self-care score – PA 3.43 ±2.09) when compared to non-app users (2.93 ±2.07) ($p = 0.0001$)
Keshawarz et al. (2018)	To compare planned LTPA levels in adults with and without T1D using an accelerometer. To examine ''diabetes-specific'' barriers to PA and explored how barriers and hypoglycaemic episodes impacted PA in people with T1D	Cross-sectional	T1D Adults Mean age: 49 ±9 yrs Mean duration of diabetes: 36 ±8 yrs Mean HbA1c: 7.7 ±1.4%	N/A	% of participants scoring a BAPAD1 item >4: Risk of Hypoglycaemia (25%) Fear of loss of control over diabetes (21%) Risk of hyperglycaemia (14%) Participants reporting barriers spent significantly less time in MVPA bouts/wk ($p = 0.047$) and engaged in significantly fewer bouts of MVPA/wk than participants who did not report barriers ($p = 0.005$) 'Diabetes-specific' barriers to PA were

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
					associated with less MVPA across all outcomes, while reporting no barriers to PA was associated with higher levels of MVPA
					Men reporting frequent hypoglycaemia spent less time in MVPA bouts/wk ($p = 0.003$) and had significantly fewer MVPA bouts/wk compared to men who reported infrequent hypoglycaemia ($p = 0.02$)
					Participants experiencing barriers were younger ($p = 0.0001$)
					Participants using CGM experienced more barriers ($p = 0.04$)
					Participants with higher HDL and lower diastolic blood pressure experienced less barriers ($p = 0.03$, $p = 0.02$)
Kneckt et al. (2001)	To evaluate whether self-esteem can determine diabetes adherence and oral health behaviour	Cross-sectional	T1D Adults Mean age: 34 ±12 yrs Mean duration of diabetes: 16 ±10 yrs Mean HbA1c: 8.5 ±1.8%	N/A	58% of those having high self-esteem had good exercise adherence, while 34% of those with low self-esteem had poor exercise adherence ($p = 0.005$)

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
Lloyd et al. (2010)	To examine the relationship between depressive symptomatology, diabetes-related distress and aspects of diabetes selfcare in a cohort of individuals with T1D	Cross-sectional	T1D Adults Mean age: 45 ±7.5 yrs Mean duration of diabetes: 36.7 ±7.1 yrs Mean HbA1c: 7.5 ±1.4%	N/A	All four PA variables were significantly and negatively correlated with the BDI (r between -0.20 and -0.27; $p < 0.01$) CESD scale (r between -0.16 and -0.33; $p < 0.01$) PAID scale (r between -0.14, $p < 0.05$, and -0.23, $p < 0.01$)
Martyn-Nemeth et al. (2017)	To examine the association of FoH with self-management behaviours	Cross-sectional	T1D (all using insulin pump) Adults (18-35 years) Mean age: 26 ±4 yrs Mean duration of diabetes: 13 ±8.1 yrs Mean HbA1c: 7.2 ±1%	N/A	FoH was associated with less PA (light activity, r = -0.341, $p = 0.045$)
McCarthy et al. (2017)	To examine patterns of PA and to identify the biological and psychosocial factors associated with PA To examine the self-management strategies employed to engage in PA	Cross-sectional	T1D Adults Mean age: 45 ±17 yrs Mean duration of diabetes: 20 ±15 yrs Mean HbA1c: 7.8 ±1.2%	N/A	Barriers to PA (BAPAD1): Work schedule (3.75 ± 2.24) Weather conditions (3.54 ± 2.06) Individuals who worked full-time had high step counts compared to other categories of employment 55,193 versus 38,295 steps ($p = 0.001$) Total BAPAD1 score negative correlated with weekly step counts

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
Pinsker et al. (2016)	To determine whether use of differing diabetes technologies affects health-related behaviours	Cross-sectional	T1D Adults Mean age: 41.4 ±16.5 yrs Mean duration of diabetes: 22.8 ±14.7 yrs	N/A	Pump users (with and without CGM) exercised less (3.8 ±1.6 days/wk) than those who did not use pump (4.54 ±1.6 day/wk; p<0.001) Participants using pump (with and without CGM) were more likely to disagree with the statement "fear of low blood glucose levels keeps me from exercising" (p<0.01) than those who did not use any devices or CGM alone
ALEXANDRA Study - Plotnikoff et al. (2010)	To investigate the utility of the Theory of Planned Behaviour in understanding PA in an adult population with T1D or T2D	Cross-sectional	T1D Adults Mean age: 51.1 ±17.1 yrs	N/A	Perceived behavioural control had a direct impact on 6-month PA in T1D group β = 0.10 (model 1) and β = 0.12 (model 2)
ALEXANDRA Study - Plotnikoff et al. (2009)	To compare PA related, key social-cognitive constructs from major health behaviour theories/models between large samples of adults with either T1D or T2D, and those without diabetes	Cross-sectional	T1D Adults Mean age: 51.1 ±17.1 yrs	N/A	T1D group reported greater cons for PA than those with T2D or without diabetes (p<0.05). "Generic population-based, theoretically driven interventions operationalizing [social-cognitive] constructs should have equal salience to adults with T1D, T2D and those without diabetes" Lower reported response efficacy (perceived benefits) scores compared to those without diabetes – suggests emphasis on the benefits of PA is required for programs targeting individuals with T1D. Greater cons in T1D group suggests emphasis should be placed on overcoming barriers to PA

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
ALEXANDRA Study - Plotnikoff et al. (2007)	To examine the predictors of PA and activity change for individuals with T1D or T2D	Cross-sectional	T1D Adults Mean age: 51.88 ±16.75 yrs Mean duration of diabetes: 21.34 ±12.89 yrs	N/A	Older age (β = -0.11 $p<0.05$) and difficulties performing tasks of daily living (β = -0.12, $p<0.05$) significantly associated with less PA Individuals diagnosed >1 yr: Higher level of PA associated with younger age at diagnosis (β = -0.11, $p<0.05$) and less perceived difficulties in tasks of daily living (β = -0.12, $p<0.05$)
ALEXANDRA Study - Plotnikoff et al. (2010)	To investigate the utility of the Protection Motivation theory for explaining PA in an adult population with T1D or T2D	Cross-sectional	T1D Adults Mean age: 51.1 ±17.1 yrs	N/A	Intention and PA behaviour were highly interrelated cross-sectionally (β = 0.30) and longitudinally (β = 0.19) Self-efficacy predictive of PA behaviour cross-sectionally (β = 0.26) and longitudinally (β = 0.20)
ALEXANDRA Study - Plotnikoff et al. (2006)	To identify key demographic and health factors associated with PA participation in adults with T1D or T2D	Cross-sectional	T1D Adults Mean age: 51.1 ±17.1 yrs	N/A	Combined model: Higher levels of PA were correlated with: Younger age (β = -0.12, $p<0.01$) Being single (β = -0.11, $p<0.01$) Higher income (β = 0.11, $p<0.01$) Lower level of perceived disability (β = -0.19, $p<0.001$)
ALEXANDRA Study - Plotnikoff et al. (2008)	To test the social cognitive theory for explaining PA in a large population sample of adults with T1D and T2D	Cross-sectional	T1D Adults Mean age: 51.1 ±17.1 yrs	N/A	Self-efficacy associated with PA (β = 0.22, $p<0.01$) Goals associated with PA (β = 0.17, $p<0.01$)

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
Raaijmakers et al. (2015)	To determine whether T1D and T2D patients' perceived autonomy support from their primary care provider, as well as their perceived competence and treatment self-regulation, are associated with their diabetes self-care activities and general diabetes control	Cross-sectional	T1D Adults	N/A	Highly educated participants engaged significantly less often in 30 min of PA than those with lower education (β = -0.73, p<0.05) Perceived competence was NOT significantly correlated with PA
Stuij et al. (2017)	To explore and describe how people with T1D and T2D in the Netherlands experience sports and PA counselling from their medical professionals in general	Cross-sectional	T1D Adults	N/A	62% disagree with this statement: "I was guided properly in taking up sports and PA (again) after my diagnosis" 38% agree / 39% disagree with this statement: "There hardly is/was any attention for sports and PA during my treatment" 37% disagree with this statement: "I find it pleasant that my HCP exert pressure on me to do more sports and PA"
Thomas et al. (2004)	To explore how much PA patients with diabetes need to perform and what are the perceived factors that prevent patients from doing more PA	Cross-sectional	T1D Adults Mean age: Active participants: 31.9 ±9.8 yrs Inactive participants: 35.9 ±6.9 yrs	N/A	Activity was not significantly associated with age or weight
Balfe et al. (2014)	To determine how and why workplace environments impact	Qualitative	T1D Adults	N/A	Barriers to PA: Commute time to/from work

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
	diabetes management for people with T1D		Age range: 23-30 yrs Mean duration of diabetes: 11.5 ±5.6 yrs		Exhausted after work Pressure to be at their desk while at work Seasonality Associated with PA: Commuting, "exhausted" after work and commute, seasonality Facilitators of PA: Good weather Partner Self-motivation
Dizon et al. (2019)	To understand patient perspectives on managing T1D during exercise	Qualitative	T1D (athletes >10 hrs/wk of PA) Adults Mean age: 41 Mean duration of diabetes: 22 yrs	N/A	Facilitators/preferred resources: Trial and error Peer-support Support from HCP Pumps, CGM and phone applications
Kennedy et al. (2018)	To explore attitudes and barriers to exercise in adults with new-onset T1D	Qualitative	T1D Adults Median age: 29 (18-53) yrs Median duration of diabetes: 66 days	N/A	Medical barriers to PA: Most frequently cited was hypoglycaemia – related to actual experience and worry about hypoglycaemia. Lack of knowledge or confidence in managing diabetes around exercise. Influence of HCP: 4 participants said HCP had advised them not to exercise Work commitments Family and other time commitments

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
					Around a half of participants reported a decline in activity levels around the time of diagnosis.
					Participants suggested education, supervised or group activity sessions, a programme of gradually increasing exercise, help with goal setting and a fitness advisor may improve activity levels
Kilbride et al. (2011)	To explore the experience of participating in exercise among people with T1D who exercise regularly	Qualitative	T1D Adults Mean age: 48.5 ±2.5 yrs Mean HbA1c: 7.35 ±0.5 %	N/A	Facilitators of PA: Trial and error Overcome FoH Understand effect of PA on their bodies Spend time adjusting insulin, food intake, monitoring and then reviewing strategies Locus of control
Kime et al. (2018)	To investigate the needs of adults with T1D around PA and the challenges they face	Qualitative	T1D Adults Age range: Women: 26-84 yrs Men: 33-91 yrs Duration of diabetes range: 2-57 yrs	N/A	Barriers to PA: Hypoglycaemia (FoH) Motivation Embarrassment Facilitators to PA: Health promotion Enjoyment To learn how PA affected their diabetes Change in culture amongst health professionals Tailored information with guidelines and instructions on how to manage activity with T1D Peer support – talking

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
					Workshops/courses PA weekend

Lascar et al. (2014)	To explore attitudes, barriers and facilitators to exercise in patients with T1D	Qualitative	T1D
			Adults
			Age range:
			  Women: 21-62 yrs
			  Men: 21-65 yrs
			Duration of diabetes range: 2 wks-50 yrs
				N/A	Barriers to PA:
					Lack of knowledge of the management of diabetes for exercise
					Time and work
					Access to facilities
					Embarrassment, body image, fear of failure
					Lack of motivation
					Weather
					
					Facilitators to PA:
					Free or reduced admission gyms/pools
					Better time management
					Support and encouragement
					Advice and information
					
					Motivators:
					Health benefits
					Body image
					Enjoyment
					Social Aspects

Martyn-Nemeth et al. (2019)	To gain knowledge about the challenges imposed by hypoglycaemia and how FoH may influence diabetes self-management behaviours	Qualitative	T1D Adults Age range: 20-57 yrs Mean duration of diabetes: 16 yrs	N/A	Barriers to PA: Hypoglycaemia High degree of planning and time required to participate in exercise Facilitators of PA: Trial and error
Oser et al. (2019)	To broaden the understanding of barriers and facilitators to	Qualitative	T1D Adults	N/A	Barriers to PA: Hypoglycaemia

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
	exercise among adults living with T1D		Age range: 19-63 yrs 40% HbA1c >9%		Burden of carrying supplies Universal barriers such as time and motivation Lack of exercise instruction from HCP Facilitators of PA: Family Online peer support Organised T1D activities Support from HCP
Colberg et al. (2015) (Colberg et al., 2015)	An overview of technology in T1D and PA	Text and Opinion	Nil	Technology e.g. wearables, pumps, monitors, calculators, artificial pancreas, pattern recognition and learning, and social integration	The overriding barrier to PA: Fear of severe hypoglycaemia, and a lack of knowledge of effective strategies for hypoglycaemia avoidance. Facilitators of PA: Technology – Activity tracking devices, insulin pumps, glucose monitors, continuous glucose monitors, artificial pancreas systems, social integration. "While technological advances have allowed exercisers with diabetes to progress toward more effectively managing their blood glucose levels during various types of PA, technology is still far from fully removing the FoH that is the strongest impediment to undertaking regular exercise with T1D"

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
Greener (2017)	The author explores the latest advice, including that of a recent consensus statement, and highlights areas where more input is needed	Text and Opinion	Nil	N/A	Barriers to PA: FoH during and after PA Concerns about losing glycaemic control Inadequate knowledge around managing diabetes when they exercise A lack of evidence about the optimal frequency, duration and intensity of exercise that improves glycaemic control Facilitators of PA: NICE guidelines for PA in T1D Consider patient's goals Further research is needed to define factors that can improve uptake and persistence in people with T1D
Kime and Pringle (2018)	Commentary: Exercise and PA in people with T1D: The importance of behaviour change	Text and Opinion	Nil	N/A	Health professionals should consider the use of behaviour theory and effective intervention strategies Programmes to have greater applicability for the average person with T1D who just wants to increase activity around daily active living and recreation
Kime and Pringle (2019)	This article outlines the importance of the role of healthcare professionals in providing advice to patients to become more physically active, and the training that could be provided to support this.	Text and Opinion	Nil	N/A	HCP need support and training around PA and T1D and behaviour change techniques

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
Narendran and Andrews (2018)	To outline the origins of EXercising for Type One Diabetes (EXTOD), a summary of what has been achieved so far, and a brief overview of future plans.	Text and Opinion	Nil	N/A	Barriers to PA: New-onset T1D: Hypoglycaemia (actual and fear of) Lack of knowledge/confidence in managing diabetes Advice from HCP to stop exercising Planning Feeling overwhelmed by diagnosis Established T1D: Loss of control of diabetes Lack of knowledge on the management of diabetes when exercising Facilitators of PA: Education program for people with T1D Peer support Engagement with patients and public to support local sporting events
National Institute for Health and Care Excellence (2018)	NICE guidelines are evidence-based recommendations for health and care in England	Text and Opinion	Nil	N/A	Advise adults with T1D that PA can reduce their enhanced cardiovascular risk in the medium and longer term. Give adults with T1D information about: Appropriate intensity and frequency of PA Role of self-monitoring of changed insulin and/or nutritional needs Effect of activity on blood glucose levels (likely fall) when insulin levels are adequate Effect of exercise on blood glucose levels when hyperglycaemic and hypoinsulinaemic

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
					Appropriate adjustments of insulin dosage and/or nutritional intake for exercise and post-exercise periods, and the next 24 hours Interactions of exercise and alcohol Further contacts and sources of information.
M. C. Riddell et al. (2017)	Author's reply to remarks by Matthew Campbell and colleagues on the consensus statement on exercise management in T1D	Text and Opinion	Nil	N/A	Barriers to PA: HCP have poor knowledge of PA and T1D Support for PA and exercise management is scarce Facilitators of PA: Health-care providers to equip themselves with knowledge to advise patients, confidently HCP to question the type and frequency of PA and any barriers to PA at each clinic visit Use of behavioural science to overcome barriers Motivational interviewing PEAK programme and EXTOD educating health professionals and patients
Sundberg (2018)	Discussion surrounding unawareness of low PA in people with T1D	Text and Opinion	Nil	N/A	Is lack of PA another social complication of diabetes? Could it be that if you are less active already from childhood, then you are less skilled in activities and thus perform them less often? Facilitators of PA: Support people with diabetes to recognise their lack of PA and identify strategies to increase PA If FoH is a major barrier to PA but not

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
					experienced hypoglycaemia, shall interventions then be targeting FoH or glycaemic variability to be most efficient?

Note. T1D – type 1 diabetes; PA – physical activity; TEE – total energy expenditure; PAL – physical activity levels; $VO_{2peak\ or\ max}$ - maximum rate of oxygen consumption; LTPA – leisure time physical activity; MVPA – moderate to vigorous physical activity; BAPAD1 – barriers to physical activity in diabetes – type 1; MET – metabolic equivalent; HDL – high density lipoprotein; BDI – Beck Depression Inventory; CESD – Centre for Epidemiological Studies of Depression; PAID – Problem Areas in Diabetes; FoH – fear of hypoglycaemia; CGM – continuous glucose monitor; HCP – healthcare professional; NICE – National Institute for Health and Care Excellence; EXTOD – exercise for type 1 diabetes; PEAK – performance in exercise and knowledge

± standard deviation

2.3   Updated Literature Search

The first literature search was conducted on 28th February 2019, then updated on 3rd February 2020 prior to publication (Brennan, Brown, Ntoumanis, et al., 2021). A final search was conducted on 1st June 2021, using the search strategy detailed in Section 2.2. Subsequent methods also followed the protocol discussed in Section 2.2.

2.3.1   Results

2.3.1.1   Article Inclusion

In the 15 months since the last search (3rd February 2020) n=440 new records were identified – see PRISMA flow diagram in Figure 2.1. A total of three additional articles were included in the updated synthesis.

Figure 2.1

Adapted preferred Reporting Items for Systematic and Meta-Analyses (PRISMA) Flow Diagram.

An updated database search dated 1st June 2021.
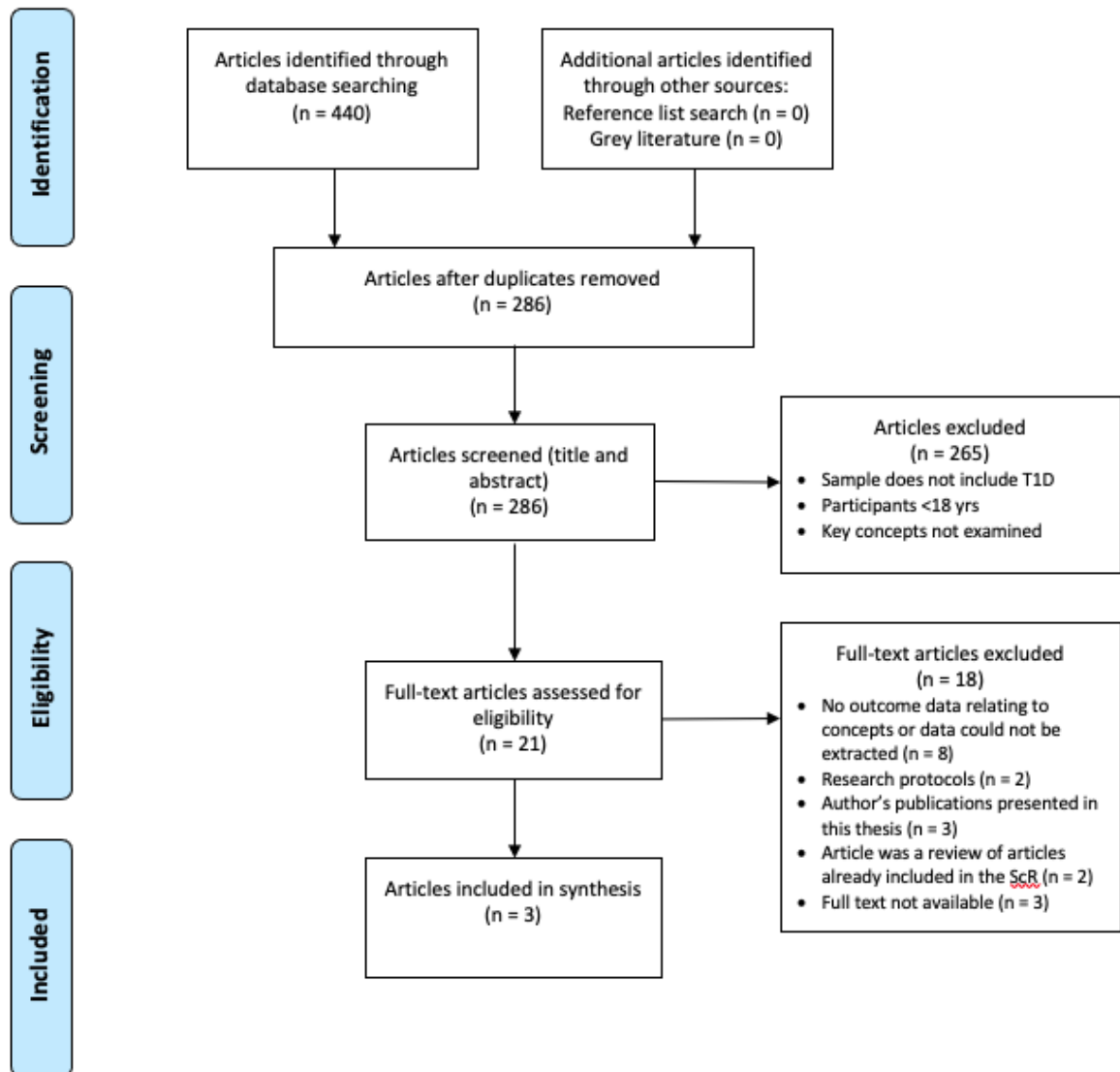
Note. T1D – type 1 diabetes; ScR – scoping review

2.3.1.2 Characteristics of Included Articles

Of the three included articles, all were in the community setting, with one each in Finland, Italy, and China. Table 2.1 shows two of the three articles were cross-sectional survey studies and the remaining article was a qualitative design. The sample sizes ranged from 13 to 1339. All articles focused on barriers to physical activity. Full details of individual sources of evidence are provided in Table 2.2. Critical appraisal was performed on the additional three included articles (Table 2.3 and Table 2.4). Higher scores within each table correspond to greater methodological quality within the hierarchical category. The two cross-sectional articles scored 8/8 and 4/8 respectively (Ahola et al., 2021; Assaloni et al., 2020), and the qualitative article scored 6/10 (Xie et al., 2020).

Table 2.1

Article Characteristics of Articles Included in Updated Synthesis

Author	Design	Sample size	Concepts		Critical appraisal score
			Barriers	Facilitators	
Ahola et al. (2021)	Cross-sectional	1339	Psychosocial factors	—	8/8
Assaloni et al. (2020)	Cross-sectional	154	Environment	—	4/8
Xie et al. (2020)	Qualitative	13	Blood glucose level variability/loss of control	—	6/10
			Time/energy/motivation/work		

Table 2.2

Individual Sources of Evidence from Included Articles in Updated Synthesis

Author	Aims	Design	Population/ participants	Intervention / control	Key findings
Ahola et al. (2021)	To investigate the association between symptoms of depression and LTPA	Cross-sectional	T1D Adults Median age: 41 (33-51) yrs	N/A	Individuals with depressive symptomatology reported lower levels of total LTPA (13.2 METh) compared to those without (19.8 METh), $p < 0.001$
Assaloni et al. (2020)	To explore PAL in Italian people with T1D before and after the national COVID 19 quarantine	Cross-sectional	T1D Adults Mean age: 45 ±12.5 yrs Mean HbA1c: 6.9 ±0.9%	N/A	Significant decrease in PA level during quarantine (Godin Scale Score 25 ±1.7) compared to pre-quarantine levels (Godin Scale Score 38.6 ±1.7 points)
Xie et al. (2020)	To establish a structured T1D self-management education programme — 'Type 1 Diabetes Education in Lifestyle and Self Adjustment' (TELSA) that is adapted to medical and cultural practices in China	Qualitative	T1D Adults Mean age (range): 31 (19-52) yrs Mean duration of diabetes: 10 (0.5-41) yrs	N/A	Barriers to PA: Glucose fluctuations during and after exercise Lack of time

Note. T1D – type 1 diabetes; PA – physical activity; TEE – total energy expenditure; PAL – physical activity levels; LTPA – leisure time physical activity; METh– weekly metabolic equivalent of task hours

± standard deviation

Table 2.3

Critical Appraisal - Analytical Cross-Sectional Studies

Citation	Q1 Were the criteria for inclusion in the sample clearly defined? It was agreed that if these details were described in earlier referenced, studies, this criterion was met	Q2 Were the study subjects and the setting described in detail? It was agreed that if these details were described in earlier referenced, studies, this criterion was met	Q3 Was the exposure measured in a valid and reliable way? It was agreed that if a valid and reliable measure existed and was available but not used, this criterion was not met	Q4 Were objective, standard criteria used for measurement of the condition? It was agreed patient-report does not constitute objective, standard criteria	Q5 Were confounding factors identified? It was agreed that this may have occurred in study design, data analysis or limitations section of the study	Q6 Were strategies to deal with confounding factors stated? It was agreed that if there were no identified confounding factors, this criterion would be marked not applicable (N/A)	Q7 Were the outcomes measured in a valid and reliable way? It was agreed that if a valid and reliable measure existed and was available but not used, this criterion was not met	Q8 Was appropriate statistical analysis used?	Score
Ahola et al. (2021)	Y	Y	Y	Y	Y	Y	Y	Y	8/8
Assaloni et al. (2020)	Y	N	Y	N	N	N	Y	Y	4/8
%	100	50	100	50	50	50	100	100	

Table 2.4

Critical Appraisal - Qualitative Research

Citation	**Q1** **Is there congruity between the stated philosophical perspective and the research methodology?** It was agreed that if a specific philosophical perspective was not stated, evidence of a sound qualitative approach would satisfy this criterion	**Q2** **Is there congruity between the research methodology and the research question or objectives?** It was agreed that if the study design was congruent with the interpretive paradigm this criterion was met	**Q3** **Is there congruity between the research methodology and the methods used to collect data?** It was agreed that if the study methods were congruent with the interpretive paradigm, this criterion was met	**Q4** **Is there congruity between the research methodology and the representation and analysis of data?** It was agreed that if the representation and analysis of data were congruent with the interpretive paradigm, this criterion was met	**Q5** **Is there congruity between the research methodology and the interpretation of results?** It was agreed that if the interpretation of results were congruent with the interpretive paradigm, this criterion was met	**Q6** **Is there a statement locating the researcher culturally or theoretically?** It was agreed that statements relating to the influence of the researcher's beliefs or values would satisfy this criterion	**Q7** **Is the influence of the researcher on the research, and vice-versa, addressed?** It was agreed that any attempt at describing this relationship would satisfy this criterion	**Q8** **Are participants, and their voices, adequately represented?** It was agreed that inclusion of participant quotes would satisfy this criterion	**Q9** **Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?**	**Q10** **Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?** It was agreed that this criterion was met if the conclusions drawn were based on the data collected	Score
(Xie et al., 2020)	U	Y	Y	Y	Y	N	N	Y	Y	U	6/10
%	0	100	100	100	100	0	0	100	100	0	

2.3.1.3 Measures of Physical Activity

Physical activity was measured in two of the three articles (Ahola et al., 2021; Assaloni et al., 2020) and like half of the included articles in the original review (Brennan, Brown, Ntoumanis, et al., 2021), both used validated self-report questionnaires; the Kuopio Ischemic Heart Disease 12 month Questionnaire (adaption of Minnesota Leisure Time Physical Activity questionnaire) and the Godin Leisure-time Exercise Questionnaire, respectively. Barriers to physical activity were measured using qualitative methods, specifically, one-on-one interviews in one article (Xie et al., 2020).

2.3.1.4 Measures of Barriers to Physical Activity

Barriers identified in the additional three included articles corresponded with existing barrier concept groups described in Section 2.2 (Brennan, Brown, Ntoumanis, et al., 2021). The barrier group, *psychosocial factors* was detailed in Ahola et al. (2021), *environment* in Assaloni et al. (2020), and *blood glucose level variability/loss of control* and *time/energy/motivation/work* in Xie et al. (2020). No facilitators to physical activity were identified.

2.3.2 Discussion

An updated database search was conducted to identify additional eligible articles published between February 2020 and June 2021. Three articles were subsequently included in the synthesis (Ahola et al., 2021; Assaloni et al., 2020; Xie et al., 2020). These articles were of mixed quality and highlighted barriers to physical activity that were categorised into existing barrier concept groups: *environment, psychosocial factors, blood glucose level variability/loss of control* and *time/energy/motivation/work* (Brennan, Brown, Ntoumanis, et al., 2021). These articles do not alter the conclusions of the scoping review (Brennan, Brown, Ntoumanis, et al., 2021) presented in Section 2.2, but do warrant further discussion.

On 11th March 2020, the World Health Organisation declared the Coronavirus (COVID-19) outbreak, a pandemic (World Health Organisation, 2020a). For many, this resulted in extended periods of 'lockdown' / 'stay at home' / quarantine orders, restricting outdoor activity along with many other routine activities of daily living. People living with T1D were included in populations most at-risk of complications from COVID-19. Not surprisingly, Assaloni et al. (2020) found that COVID-19 quarantine was associated with decreased physical activity levels in Italian adults living with T1D during the period of quarantine. Though there were some methodological concerns with this article, it adds to the

quantitative pool of articles examining *environment* as a barrier to physical activity. Although articles exploring the impact of COVID-19 are likely to grow as time goes on, the updated literature search does not meaningfully alter the position of *environment* as a barrier to physical activity in adults living with T1D.

Adding to one of the more prominent barrier groups, *psychosocial factors*, Ahola et al. (2021) found that individuals experiencing depressive symptomatology reported lower levels of total leisure time physical activity compared to those without symptoms. This finding is similar to an existing cross-sectional investigation included in the scoping review exploring the relationship between depressive symptomatology and aspects of selfcare, including physical activity (Lloyd et al., 2010). Both articles were of sound methodological quality and used the Beck Depression Inventory to measure symptoms of depression, though their measurement of physical activity differed. This additional article does not challenge findings from the initial literature review, rather further supports the notion that *psychosocial factors* are a prominent barrier to physical activity in people living with T1D.

In developing a diabetes structured education program, Xie et al. (2020) undertook semi-structured interviews with adults living with T1D in China to understand their needs. Although the aim of the study was not to identify barriers to physical activity, in trying to understand participants' needs, the authors found that the biggest obstacle to physical activity was glucose fluctuations and a lack of time. These barriers fit within existing barrier groups, *blood glucose level variability/loss of control* and *time/energy/motivation/work*. Xie et al. (2020) used qualitative enquiry (with some fundamental methodological flaws) to identify *time/energy/motivation/work* as a barrier which mimics the majority of original articles and consolidates the original review findings. Although *blood glucose level variability/loss of control* was identified for the sixth time as a barrier, it does not alter the position of this barrier in the overall synthesis (Xie et al., 2020).

The purpose of updating the search was to identify any crucial contributions to the body of literature that may have been missed over the 15-month period since the initial search. Three articles were included in the final synthesis and although they did not alter the conclusions of the original review, they consolidated the original findings and gaps in the literature. These gaps guided the subsequent study and included: the lack of robust RCTs to establish the feasibility, acceptability, and efficacy of theoretically sound behaviour change interventions targeting hypoglycaemia, FoH, and other psychosocial factors; exploration of barriers to physical activity through a mixed method approach; and a lack of consistent and reputable information communicated by health professionals.

2.4 Limitations

The choice of review type was guided by a preliminary search of the literature which outlined an emerging field of research and heterogeneity among a small number of studies. The scoping review identified and mapped types, sources, and quality of available evidence and knowledge gaps, but as a method, scoping reviews do have some limitations. The scoping review presented in section 2.2 was not designed to answer a specific clinical question nor to provide clinical guidance relating to treatment or management of type 1 diabetes. This review provides recommendations for future research and reviews but is unable to provide guidance on effectiveness or feasibility (Peters et al., 2017). Future robust experimental designs, preferably fully powered RCTs are required before systematic and or meta-analyses can be performed in this area.

Chapter 3   Research Methodology and Whole-of-Study Methods

The systematic scoping review presented in Section 2.2 called for robust interventions to address psychosocial factors, and diabetes-specific barriers to physical activity, specifically hypoglycaemia and FoH (Brennan, Brown, Ntoumanis, et al., 2021). The review recommended that a mixed method approach was necessary to enrich understanding of barriers faced by those living with T1D. The Medical Research Council also advocate for mixed methods evaluation of complex interventions, particularly in the feasibility phase (O'Cathain et al., 2019). A mixed method study was designed to explore the feasibility, acceptability, and preliminary efficacy of a pre-existing, theory-driven intervention to address FoH as a barrier to physical activity (Section 3.4.2). Mixed methods study objectives, outcomes, and outcome measures are shown in Table 3.1 .

The intervention, Type 1 TACTICS for Exercise©, was a pre-existing self-management education program developed by Diabetes WA® in 2017. Although it is beyond the scope of the thesis to describe intervention development, it was developed by an experienced, multidisciplinary team of diabetes health professionals after a local gap in services was identified. Underpinning theories were chosen to target key behaviours and are described in greater detail in Section 3.4.2.1. An earlier exploratory study indicated the program may potentially reduce fear of hypoglycaemia as a barrier to physical activity and further program iteration and evaluation was recommended (Brennan & Brown, 2019). The intellectual property owners of the program, Diabetes WA®, subsequently revised the program in accordance with these findings. A systematic scoping review followed and verified that hypoglycaemia and FoH are prominent barriers to physical activity and are not addressed by existing interventions, further consolidating the need for an evidence-informed intervention in this area.

Table 3.1

Mixed Methods Study Objectives, Outcomes, and Measures

Objectives	Outcome	Outcome measure	Timepoint[†]	Publication
	Feasibility outcomes			
To assess the feasibility and acceptability of procedures across the study schedule	• Feasibility of study procedures • Acceptability of study procedures	• Time and resources involved • Recruitment rate • Participant numbers: expressions of interest; screened; enrolment; allocation; attendance at t_1 and t_2; completion of t_3 • Characteristics of recruited participants and dropouts • Nature of missing data from questionnaires • Internal reliability of investigator developed tools • Semi-structured focus group interviews	$-t_1 - t_4$	Brennan, Albrecht, et al. (2021) Brennan, Brown, Leslie, et al. (2021)
To determine the acceptability of the intervention and control	• Acceptability of intervention • Acceptability of control	• Intervention / control fidelity assessment • Attrition from allocation – $t_1 - t_2$ • Semi-structured focus group interviews	t_{0-4}	Brennan, Albrecht, et al. (2021) Brennan, Brown, Leslie, et al. (2021)
	Efficacy outcomes			
To examine the preliminary effects of the intervention and control workshops on primary and associated secondary outcomes	Primary outcome: 1. FoH as a barrier to PA Secondary outcomes: 2. Self-efficacy to participate in PA and manage associated blood glucose excursions 3. Attitudes and intentions towards PA 4. Participation in PA 5. Diabetes distress 6. Well-being	1. Barriers to Physical Activity in Diabetes – type 1 (BAPAD1) (Dubé et al., 2006) 2. Scale developed using Bandura's guide for constructing self-efficacy scales (Bandura, 2006) 3. Scale developed using Fishbein and Ajzen (Fishbein & Ajzen, 2010) 4. International Physical Activity Questionnaire - short form (IPAQ-SF) (International Physical Activity Questionnaire, 2005) 5. Problem Areas In Diabetes (PAID) scale (Polonsky et al., 1995) 6. World Health Organisation – 5 (WHO-5) Well-Being Index (Topp et al., 2015) • Semi-structured focus group interviews	t_{1-4}	Brennan, Albrecht, et al. (2021) Brennan, Brown, Leslie, et al. (2021)

Note. FoH – fear of hypoglycaemia; PA – physical activity

† $-t_1$ – enrolment; t_0 – allocation; t_1 –initial workshops; t_2 – booster workshops; t_3 – 8 weeks after t_2; t_4 – focus groups
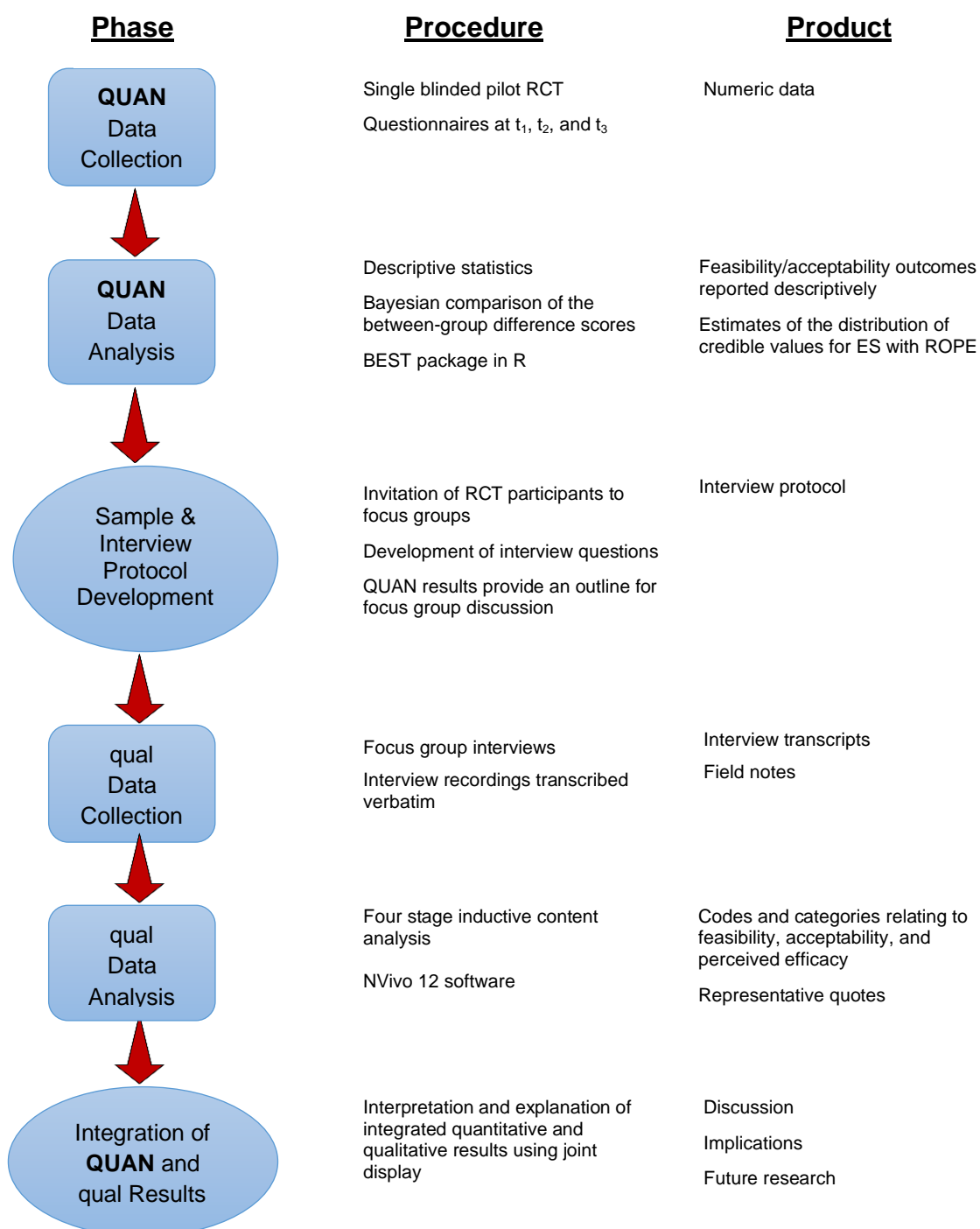
3.1 Study Design and Whole-of-Study Procedures

The study is situated in a mixed methods research paradigm that benefits from epistemological and methodological pluralism (Johnson & Onwuegbuzie, 2004; Tashakkori & Teddlie, 2003). Pragmatism has long been considered a philosophical partner for mixed methods research (Greene, 2008; Johnson & Onwuegbuzie, 2004; Morgan, 2014; Tashakkori & Teddlie, 1998) to solve practical problems in the constantly changing real world (Creswell & Plano Clark, 2018). It rejects traditional assumptions about the nature of reality, knowledge, and inquiry, and accepts that there can be single or multiple realities that are open to empirical inquiry and can only be encountered through human experience (Creswell & Plano Clark, 2018; Tashakkori & Teddlie, 1998). A non-purist approach allows the strengths of one approach (quantitative or qualitative) to offset the weaknesses of the other (Creswell & Plano Clark, 2018).

The study employed a pragmatic, two phase, explanatory sequential mixed methods design (Figure 3.1) (Creswell & Plano Clark, 2018). This design consists of two distinct phases: quantitative (questionnaires) followed by qualitative (focus group interviews). Emphasis was placed on the quantitative phase of this study as depicted by '**QUAN'** versus 'qual' in Figure 3.1. A steering group was assembled to guide the study from recruitment through to dissemination. The quantitative component of the study was a single-blind pilot RCT. Participants were recruited, screened, and provided consent before they were randomised into either the intervention (Type 1 TACTICS for Exercise©) or control (standard care) group. Self-administered questionnaires were completed by both arms of the study immediately before initial intervention/control workshops, immediately before booster intervention/control workshops, and 8-weeks after booster workshops. The qualitative component consisted of small, face-to-face focus group interviews. Participants were recruited by email from those who did not withdraw from the RCT and remained blinded to their study arm until the conclusion of the interview. Semi-structured interviews were audio-recorded, de-identified, and transcribed verbatim. Data integration followed and is the interface between qualitative and quantitative results and procedures (Creswell & Plano Clark, 2018). Integration was achieved at three levels: design, methods, and interpretation and reporting (Fetters et al., 2013).

Figure 3.1

Visual Model of Mixed Methods Sequential Design.

An explanatory sequential strategy was used to collect and analyse quantitative data before using qualitative data to build on quantitative results.

Phase	Procedure	Product
QUAN Data Collection	Single blinded pilot RCT Questionnaires at t_1, t_2, and t_3	Numeric data
QUAN Data Analysis	Descriptive statistics Bayesian comparison of the between-group difference scores BEST package in R	Feasibility/acceptability outcomes reported descriptively Estimates of the distribution of credible values for ES with ROPE
Sample & Interview Protocol Development	Invitation of RCT participants to focus groups Development of interview questions QUAN results provide an outline for focus group discussion	Interview protocol
qual Data Collection	Focus group interviews Interview recordings transcribed verbatim	Interview transcripts Field notes
qual Data Analysis	Four stage inductive content analysis NVivo 12 software	Codes and categories relating to feasibility, acceptability, and perceived efficacy Representative quotes
Integration of **QUAN** and qual Results	Interpretation and explanation of integrated quantitative and qualitative results using joint display	Discussion Implications Future research

Note. QUAN – quantitative, qual – qualitative, RCT – randomised controlled trial, ES – effect size, ROPE – region of practical equivalence, SD – standard deviation

t_1 –Initial workshops, t_2 – Booster workshops, t_3 – 8 weeks after t_2

Adapted from Ivankova et al. (2006); Tashakkori and Teddlie (2003)

This chapter reports the overall approach used for the mixed methods study. Methods exclusive to either the quantitative or qualitative aspects of the study (inclusion / exclusion criteria, recruitment, data collection, analysis, and interpretation) are reported in the following publications, presented in Chapter 4:

Brennan, M. C., Albrecht, M. A., Brown, J. A., Leslie, G. D., & Ntoumanis, N. (2021). Self-management group education to reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes: A pilot randomised controlled trial. *Canadian Journal of Diabetes, S1499-2671(21)00001-0. Advance online publication.* https://doi.org/10.1016/j.jcjd.2021.01.001

Brennan, M. C., Brown, J. A., Leslie, G. D., & Ntoumanis, N. (2021). The acceptability of self-management group education to reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes: A mixed methods approach. *Canadian Journal of Diabetes. Advance online publication.* https://doi.org/10.1016/j.jcjd.2021.04.008

Where it was not possible to describe certain aspects of quantitative or qualitative methods in the above publications, a comprehensive account is described in this chapter.

3.1.1 Integration Through Design

The explanatory sequential design of this study places an emphasis on the quantitative approach and calls on the qualitative data to expand and explain the quantitative data (Creswell & Plano Clark, 2018; Fetters et al., 2013; Ivankova et al., 2006). Although discrete analysis of the quantitative data provided insights into the primary and secondary outcomes, it did not encompass reasons as to why or how certain phenomena occurred. Integrated qualitative inquiry expanded on and provided explanations of these phenomena and of participants' experience (Fetters et al., 2013). Design integration was pivotal in answering the research questions, particularly those concerning feasibility and acceptability of the study design and intervention.

3.1.2 Integration Through Methods

Integration via data collection methods occurred in several ways: *embedding, connecting,* and *building* (Creswell & Plano Clark, 2018; Fetters et al., 2013). *Embedding* is defined by Creswell (2009) as "a complex integration technique that entails linking the qualitative and quantitative data through connecting, building, or merging at multiple interfaces" (p. 208). The qualitative data was *embedded* as a secondary, complementary dataset within the

larger study to understand contextual factors that influenced quantitative findings and to understand participants' experience of the intervention and study procedures (acceptability). *Connecting* occurs when the quantitative and qualitative research are connected between data analysis of the first phase and data collection of the second phase of research (Creswell, 2009). In this study, integration through *connecting* occurred when quantitative data linked to qualitative data through the *sampling frame*; participants who did not withdraw from the RCT were invited to attend a focus group interview (Fetters et al., 2013). Integration via *connection* ensured meaningful interaction with focus group participants who were able to offer thoughtful and considered accounts of their experience in the RCT. *Building* occurs when one dataset informs the data collection approach of the other (Fetters et al., 2013). In this study, data were integrated through *building* by identifying specific quantitative results (identified in Figure 5.1 and Table 5.1) that called for additional explanation and then used these results to guide the development of the focus group interview questions (Creswell & Plano Clark, 2018). This form of integration enhanced the development and refinement of qualitative data collection instruments, allowing preliminary quantitative findings to be explored and corroborated, hence improving the validity of the outcome data (Fetters et al., 2013).

3.1.3 Integration Through Interpretation and Reporting

Integration of quantitative and qualitative data at the interpretation and reporting phase occurred using a *staged* approach, followed by a *joint display* (Creswell & Plano Clark, 2018; Fetters et al., 2013). Quantitative and qualitative results were initially analysed and published separately (see Chapter 4). Data were then brought together using a visual, joint display (Figure 5.1 and Table 5.1). This visual display first shows how key findings of the systematic scoping review informed the mixed methods study objectives. Quantitative and qualitative results are then presented alongside whole-of-study outcomes and implications. This integration results in higher quality inferences and highlights the elaborating purpose of the explanatory sequential design (Tashakkori & Teddlie, 2003). After presenting quantitative and qualitative results side-by-side, the *fit* of data integration was determined, that is, how the qualitative results *confirmed*, *explained,* and or were *discordant* to quantitative findings (Creswell & Plano Clark, 2018; Fetters et al., 2013). *Confirmation* occurred when the qualitative and quantitative findings confirmed the results of each other, improving the credibility of the findings. *Expansion* occurred when the qualitative results expanded or explained the quantitative findings, addressing different or complementary aspects of a single phenomenon of interest. *Discordance* occurred when quantitative and qualitative findings were incongruent, inconsistent, or were in conflict with

one another (Fetters et al., 2013). A narrative discussion of how these meta-inferences relate and compare to the original systematic scoping review findings is provided in Chapter 5.

3.2   Analysis

Quantitative data pertaining to participant baseline characteristics, feasibility, and elements of acceptability were analysed and reported descriptively. Bayesian comparison of between-group effect size difference was used to analyse questionnaire data (Kruschke, 2013). Focus group interview transcripts were analysed using the 4-stage inductive content analysis approach (Bengtsson, 2016). A comprehensive description of discrete data analysis methods of the quantitative and qualitative data are described in Section 4.1 and 4.2 respectively (Brennan, Albrecht, et al., 2021; Brennan, Brown, Leslie, et al., 2021).

3.3   Steering Group

The steering group formation aligned with the National Health and Medical Research Council and Consumers Health Forums' statement on *Consumer and Community Involvement in Health and Medical Research* (Consumers Health Forum of Australia, 2016). Involving consumers and community in research allows their experience, values, and priorities to shape research, policies, and practice. The steering group for this study was formed with the assistance of the Consumer and Community Involvement program, a platform of the Western Australian Health Translation Network. Type 1 diabetes consumers[1] responded to an advertisement distributed via Consumer and Community Involvement program and Diabetes WA® e-communications. Interested consumers registered with the Network and underwent a selection process conducted by the Consumer and Community Involvement program. Suitable applicants were later presented to the researcher (PhD candidate) who selected four T1D consumer representatives. Type 1 diabetes consumers were renumerated in accordance with Consumer and Community Involvement program guidance. Diabetes health professionals were also invited to join the project steering group and included credentialled diabetes educators (4), an endocrinologist (1), a clinical psychologist (1), and a representative from local and national diabetes bodies (1), who all agreed to participate after being approached directly based on their experience, relevance, and stakeholdership. All steering group members agreed

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[1] The phrase, 'type 1 diabetes consumers' refers to the consumption of a product, Type 1 TACTICS for Exercise© rather than diabetes as a condition.

on Terms of Reference (Appendix D.3) and T1D consumer members signed a confidentiality agreement (Appendix D.4).

The steering group met face-to-face for 60 minutes on six occasions and provided input via email correspondence throughout the project. An overview of the steering group's input and influence over the course of the study is provided in Table 3.2.

Table 3.2

Steering Group Contributions

Meeting	Topics discussed	Influence on study/project
2nd October 2018 (T1D consumer only meeting)	• Introductions • Background to project • Meeting preferences • Honorarium payments • Terms of Reference and confidentiality • Questions and concerns	• Developed protocol for scheduling future steering group meetings

16th October 2018	• Introductions
	• Project outline
	• Group preferences
	• Recruitment and recruitment material
	• QAs (input via email)
		• Planned future meetings
		• Informed Participant Information Statement (for RCT and FG)
		   ○ Content
		   ○ Readability
		• Informed participant information at the start of QAs
		• Informed wording of recruitment material
		• Informed the 'angle' of recruitment
		• Informed recruitment strategy
		   ○ Use multiple versions of posters/material to target different cohorts
		   ○ Informed what hospitals, primary health and community services to target
		• DWA confirmed assistance they can provide:
		   ○ Include in all DWA online media
		   ○ Mass email distribution
		• Influenced the wording, flow, readability, and usability of participant QAs
		   ○ Identified technical glitch in QA

21st January 2019	• Recruitment plan • Intervention / control scheduling • Participant resources	• Informed recruitment strategies including in-person visits to tertiary and private clinics to talk to potential participants • Informed how social media was used to attract participants • Informed DWA's ongoing involvement in recruitment process • Informed study processes around advertising, expressions of interest, screening, consent, randomisation, and scheduling of participants • Informed intervention / control locations and times • Informed exercise diary layout, content, and readability • Informed exercise intensity handout layout, content, and readability • Informed the creation of a participant take-home booklet

Meeting	Topics discussed	Influence on study/project
7th March 2019	• Revised recruitment material and plan • Feedback on take-home booklet • Facebook group	• Defined strategy to recruit via GPs and RACGP and private diabetes educators • Further adjustments to take-home booklet • Informed topic guide for Facebook posts • Provided guidance surrounding how the investigator should interact with Facebook group • Established T1D consumer involvement as Facebook group administrators • Ensured Facebook content was relevant and relatable to people living with T1D
25th August 2020	• Preliminary results • Dissemination of results	• Clarified use of terminology around *fear of hypoglycaemia as a barrier to physical activity* • Informed how to explain results to health professionals • Informed how to explain results to people living with T1D • Guided the dissemination evening for T1D community
3rd December 2020	• Where to from here? • Utility of intervention to improve PA participation	• Provided ideas for future intervention iterations, particularly how to use peer-led support groups

Note. T1D – type 1 diabetes; RCT – randomised controlled trial; FG – focus group; QA – questionnaires; DWA – Diabetes WA®; GP – general practitioner; RACGP – The Royal Australian College of General Practitioners; PA – physical activity

3.4   Workshops

To further describe the intervention and control workshops highlighted in Chapter 4, the following section provides greater detail of the control content, as well as context and rationale for included behaviour change theories and behaviour change techniques (BCT).

3.4.1   Control

Randomised controlled trials of health care interventions often use 'standard care' as a control condition (Freedland et al., 2011). The standard care (control) arm of the RCT aimed to represent widely available content on the topic of physical activity and T1D. A control arm is presumed to experience the same conditions of an RCT except the intervention so that when compared, the intervention effects can be isolated (Jewkes et al., 2020). As such, the following standard care arm aimed to provide a control for the "group effect" that may be observed when gathering like-minded individuals with T1D. As 'standard care' can differ greatly between and within countries, and even for the same condition (Ayling et al., 2015b), a detailed description is given below. The following complements details reported in Sections 4.1 and 4.2 relating to control content, facilitator communication skills, and fidelity of delivery.

Participants in the control arm were invited to attend a one-hour, face to face session via a PowerPoint presentation in a didactic style by the same facilitator delivering the intervention workshops. It involved dissemination of the following content:

- Standard physical activity guidelines

- Basic information on the effects of physical activity on BGLs

- Target BGLs

- Safety considerations including how to recognise and treat hypoglycaemia.

This was followed by a further one-hour booster workshop, four weeks later, which involved:

- A review of how to recognise and treat hypoglycaemia as a result of physical activity

- Information on how to safely progress physical activity

- Existing services available in the community.

3.4.2 Intervention

The intervention, Type 1 Tactics for Exercise© was a pre-existing, Diabetes WA® group self-management education workshop which consisted of an initial session (3 hours), a booster session (1 hour) 4 weeks later, and a peer-led private Facebook group (after attendance of the initial session). Intervention content, theory and behaviour change theories were mapped and are presented in Table 3.3 and in the publication by Brennan, Albrecht, et al. (2021) (Section 4.1). The consensus statement by Michael C. Riddell et al. (2017) detailing current evidence-based strategies to manage blood glucose for physical activity was used to guide the development of the intervention content. The facilitator used communication skills and behaviours consistent with Social Cognitive Theory (Bandura, 1977) and Dual Process Theory (Chaiken et al., 1996) to deliver the program content. The intervention workshops were run face-to-face by a facilitator (PhD candidate, MB) who is an accredited exercise physiologist and credentialled diabetes educator. Groups were facilitated in regional and metropolitan locations in Western Australia with individual group size limits set at between 2 and 12 participants. Appropriate permissions were sought from the intellectual property owners, Diabetes WA® (Appendix D.5).

Table 3.3

Type 1 TACTICS for Exercise© Program Summary

Section	Content	Theoretical Components	Behaviour Change Techniques*
Section 1: Introduction, housekeeping and program overview	• Questions • Current PA recommendations • Barriers to PA • Program overview	• Skills Mastery – self-reflection	1.2; 5.1; 6.2
Section 2: Carbohydrate metabolism	• Metabolic and endocrine response to PA in people with and without T1D	• Systematic Processing • Open discovery questions • Skills Mastery – self-reflection • Physical and psychological affect • Verbal Persuasion	5.1; 6.2; 16.3
Section 3: Preparing for exercise	• Planning for PA • Contraindications/considerations for PA	• Verbal Persuasion • Skills Mastery – self-reflection	11.3; 16.3
Section 4: Blood glucose levels	• Monitoring BGL • Targets • Introduce the 'timeline activity'	• Verbal Persuasion • Skills Mastery – self-reflection	6.2; 8.6; 11.3; 15.3; 16.3
Section 5: Carbohydrate intake	• Recommended carbohydrate intake for PA • Build timeline activity to include carbs	• Skills Mastery • Role Modelling • Skills Mastery	4.1; 4.2; 6.1; 6.2; 8.1; 8.7; 9.3; 11.3; 15.3; 16.3
Section 6: Insulin	• Insulin pharmacokinetics • Use timeline activity to explore the effect of bolus insulin • Basal insulin	• Skills Mastery • Role Modelling • Skills Mastery	4.1; 4.2; 6.1; 6.2; 8.1; 8.7; 9.3; 11.3; 15.3; 16.3
Summary	• Exercise diary • Facebook support group and/or email contact • Review key messages • Reflection	• Verbal persuasion • Skills mastery	2.3; 3.1; 3.3; 4.2; 5.4

Goal setting	• My Action Plan worksheet	• Verbal persuasion • Role modelling	1.1; 1.2; 1.3; 1.4; 15.1

Type 1 TACTICS for Exercise© – Booster Session

Section 1: Introduction	• Welcome participants back • Ask group about their goals from four weeks ago • Questions	• Verbal persuasion • Role modelling – sharing obstacles	5.4; 6.2; 15.1
Section 2: Scenarios	• Discuss PA scenarios • Work through scenarios from last four weeks	• Skills mastery • Verbal persuasion • Physical and Emotional Management	3.1; 3.3; 4.2; 5.4; 6.1; 6.2; 8.1; 11.3; 15.3; 16.3
Section 3: Conclusions	• Revisit barriers to PA from four weeks ago • Revisit burning questions from four weeks ago • Revisit goal setting	• Role modelling • Verbal persuasion • Skills mastery	1.1; 1.2; 1.3; 1.4; 2.3; 3.1; 3.3; 4.2; 8.7; 15.1

Note. PA – physical activity; T1D – type 1 diabetes; BGL – blood glucose level

*Coded using the the Behaviour Change Technique Taxonomy (v1) (Michie et al., 2013)

Adapted from Brennan, Albrecht, et al. (2021)

3.4.2.1 Behaviour Change Theories Underpinning the Intervention

While knowledge and skill are involved in the process of behaviour change, information giving is rarely successful in changing health behaviour (Hagger & Luszczynska, 2014; Knight et al., 2006). Programs utilising psychosocial concepts such as self-efficacy are required to facilitate behaviour change, particularly physical activity (Bandura, 1997; Knight et al., 2006; Luszczynska & Schwarzer, 2005). A systematic review and meta-analysis of behavioural interventions for young people with T1D found that there was no mention of theory in 56% of published RCTs (Ayling et al., 2015a). Social Cognitive Theory was the principal behaviour change theory, present in every section of the intervention, and Dual Process Theory (systematic process) was used in a lesser capacity to facilitate learning of the metabolic and endocrine response to physical activity.

3.4.2.1.1 Social Cognitive Theory

Figure 3.2 illustrates Social Cognitive Theory which describes self-efficacy, outcome expectations, goals, and barriers and facilitators as key constructs of behaviour change (Bandura, 1977; Luszczynska & Schwarzer, 2005). The first factor central to Social Cognitive Theory is perceived self-efficacy – a person's belief in their capability to perform a specific action to attain a desired outcome (Bandura, 1977, 2004). This personal sense of control means individuals are more inclined to take action and feel more committed to the decision to do so (Luszczynska & Schwarzer, 2005). Unless people believe they can perform desired behaviours, they are unlikely to act or persevere in the face of challenges (Bandura, 2004). Bandura outlines four key sources of self-efficacy: mastery experience, role modelling, verbal persuasion, and physiological and affective states (Bandura, 1997); these sources are discussed in more detail in Section 3.4.2.1.3. Figure 3.2 exhibits the paths of influence on behaviour where self-efficacy affects health behaviour both directly and indirectly through goals, outcome expectations, and perceived socio-structural barriers and facilitators of behaviour (Bandura, 2004).

Outcome expectations is another core component of Social Cognitive Theory and refers to people's beliefs about the possible consequences or outcomes of their actions which are shaped by past experiences. Physical outcome expectations can relate to positive or negative effects of the behaviour. For example, anticipating hypoglycaemia as a result of physical activity versus expectant long-term stability in BGLs as a consequence of physical activity. Social approval and disapproval relating to the behaviour within the person's interpersonal relationships is another key aspect of outcome expectations. Social

modelling, where individuals generate new behaviour patterns by observing relatable others, can motivate the individual by introducing behavioural outcome expectations (Luszczynska & Schwarzer, 2005). The final feature of outcome expectations is a person's self-evaluative reactions to the behaviour. People are inclined to do things that give them self-satisfaction and self-worth, while avoiding activities that are not conducive to such outcomes.

Goals that relate to outcomes of personal interest and that the person values, enhance motivation to achieve that goal. Realistic, short-term attainable goals increase the likelihood of behaviour change by reinforcing action and effort associated with success.

Perceived barriers and facilitators of the desired behaviour are the final determinant of behaviour change proposed by this theory. Barriers and facilitators can be personal (e.g., energy, mood, weather) or situational (e.g., health systems). These play a key role in self-efficacy assessment as self-efficacy beliefs are measured against barriers to successful performance.

Figure 3.2

Key Constructs of Social Cognitive Theory.

Adapted from Bandura (2004)
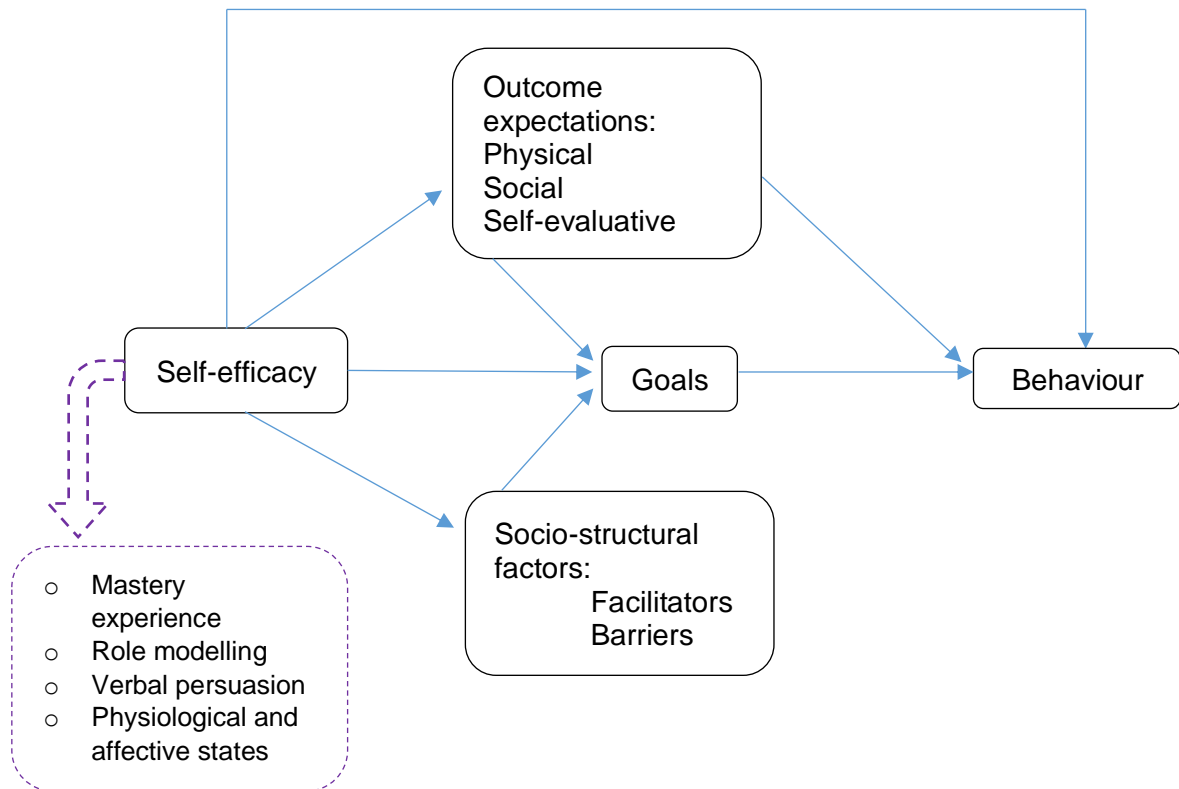
Bandura further developed Social Cognitive Theory to include the model of reciprocal determinism (Figure 3.3), whereby personal, environmental, and behavioural factors constantly interact (Bandura, 1997). These dynamic relationships can be negative or positive, for example personal factors may limit or facilitate behaviour and behaviour may change personal factors (Baranowski, 1990).

Personal or cognitive determinants featured in Type 1 TACTICS for Exercise[©] include knowledge, skill, self-efficacy, physiological and affective states, and goals. A person may have high intentions to increase physical activity because they expect it to reduce risk of cardiovascular complications (positive outcome expectancy), but they may lack the technical skills and knowledge to titrate insulin in response to activity and hence find activity too challenging to pursue. Environmental factors may include social environment (support and influence) and physical environment (opportunities and access to equipment). A person may exhibit favourable personal factors (skill and knowledge) but lack access to important diabetes technologies such as government subsidised continuous glucose monitoring, which may then negatively impact on personal factors

(self-efficacy). Behavioural factors may consist of many smaller behaviours which are important to identify so it is clear which behaviour relates to environmental and personal factors (Bandura, 1997; Baranowski, 1990).

Figure 3.3

Social Cognitive Theory: An Example of Reciprocal Determinism in Type 1 TACTICS for Exercise©

Personal / Cognitive Factors

Knowledge

Skill

Self-efficacy

Physiological and affective states

Goals

Environmental Factors

Observational learning / role modelling

Verbal persuasion from peers

Opportunity/access

Social support

Behavioural Factors

Attempting new strategies to manage BGLs for PA

Physical Activity

Mastery experiences
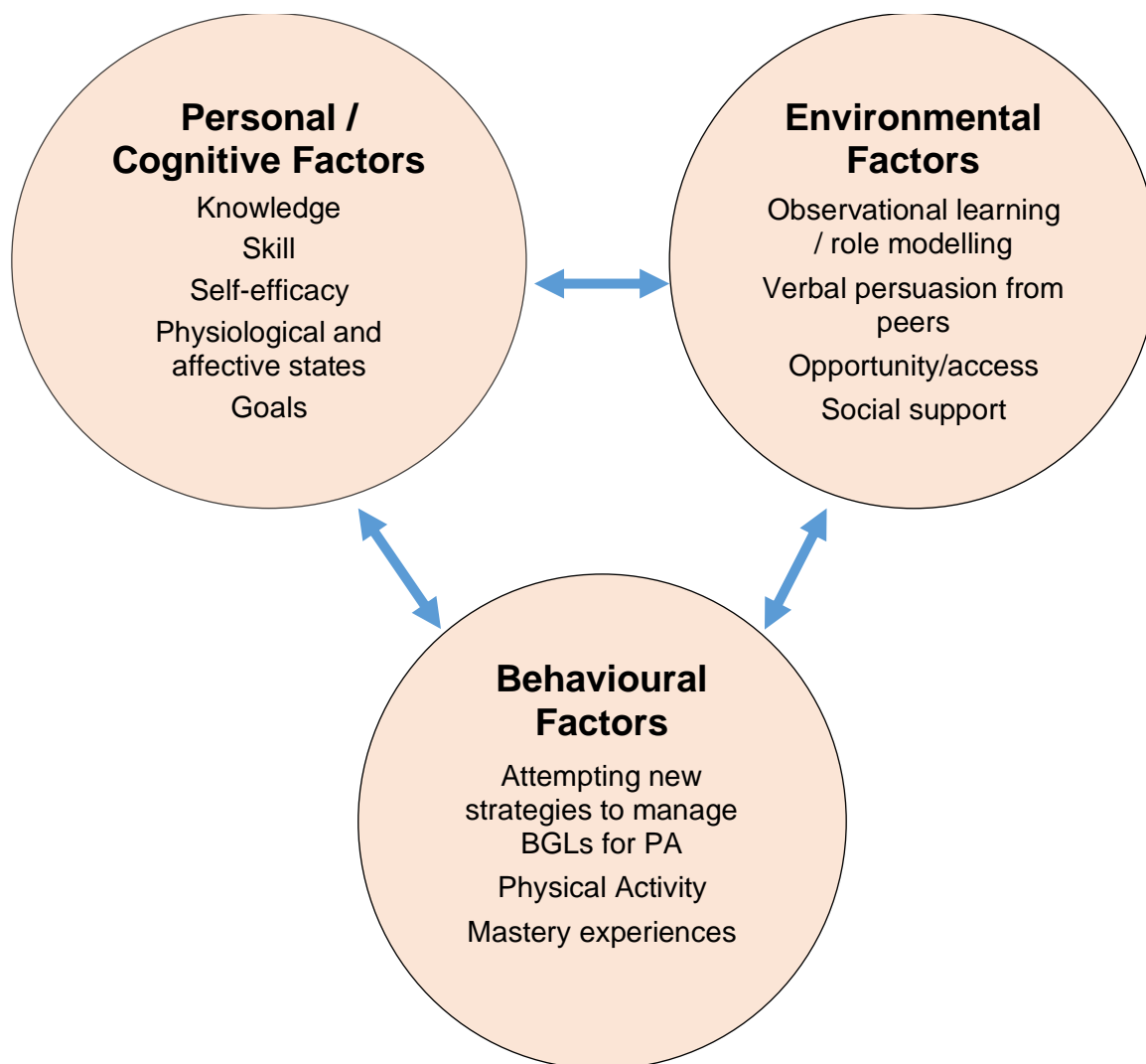
Note. PA – physical activity, BGLs – blood glucose levels

Adapted from Bandura (1997)

Social Cognitive Theory has been used widely in physical activity interventions in the general population and is one of the most common behaviour change theories used in the management of chronic health conditions (McDermott et al., 2016; Painter et al., 2008; Petosa et al., 2003; Plotnikoff et al., 2013; Young et al., 2014). The literature suggests Social Cognitive Theory can explain approximately 30% of the variance in objective and self-reported physical activity (Plotnikoff et al., 2013; Young et al., 2014), and up to 48% of

the variance for intention to participate in physical activity (Plotnikoff et al., 2013). The reported variance in physical activity behaviour explained by Social Cognitive Theory in the general population meets recommendations ($R^2 \geq 0.3$) for a theory to be considered a useful framework for intervention design (Baranowski et al., 1998).

A number of studies have discussed the relationship between Social Cognitive Theory and physical activity in the T1D population (Allen, 2004; Plotnikoff et al., 2008). The effects of Social Cognitive Theory variables on physical activity were tested in a longitudinal study of a T1D sample of 697 (Plotnikoff et al., 2008). The explained variance of goals and physical activity behaviour was $R^2=0.52$ and $R^2=0.14$, respectively. Self-efficacy was the main predictor of goals and physical activity behaviour in T1D sample (ß=0.59 and ß=0.22, respectively) and was significantly interrelated with positive outcome expectancies (ß=0.5). An earlier integrative literature review also found that Social Cognitive Theory (and more specifically, self-efficacy) was predictive of exercise initiation and maintenance over time in people living with T1D and T2D (Allen, 2004). These studies provide evidence for the utility of Social Cognitive Theory in diabetes samples and recommend targeting self-efficacy to set goals and change behaviour (Allen, 2004; Plotnikoff et al., 2008).

Interventions targeting physical activity in adults living with T1D are limited (Brennan, Brown, Ntoumanis, et al., 2021). One pilot RCT (Brazeau et al., 2014) examined the efficacy of a theory-driven physical activity intervention in an adult T1D sample. The intervention was designed and developed based on the Theory of Planned Behaviour (Ajzen, 1991) and Social Cognitive Theory (Bandura, 1977) and found an increase in cardiorespiratory fitness, but not in total energy expenditure. The Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) collaborative heavily featured Social Cognitive Theory in their self-management group education program for people living with T2D (Skinner et al., 2003). The collaborative found short to medium term improvements to self-reported physical activity, body weight, triglyceride levels, and key health beliefs (Davies et al., 2008; Khunti et al., 2012). Further real-world evaluation of the program revealed significant reduction in HbA1c at six and 12-months (Chatterjee, Davies, Stribling, et al., 2018).

Despite the evidence suggesting the utility of Social Cognitive Theory in diabetes samples for physical activity behaviour change and self-efficacy, there remain few experimental studies demonstrating its use in physical activity behaviour change in the T1D adult population (Brazeau et al., 2014; Pillay et al., 2015). The current study will contribute to addressing this gap in the literature by using Social Cognitive Theory to underpin Type 1

TACTICS for Exercise©. The Theory's key constructs of behaviour change (self-efficacy, outcome expectations, goals, and barriers and facilitators) have guided the intervention design and key outcome measures (self-efficacy, attitudes, intentions, and barriers) to determine its potential to improve physical activity behaviour change in the T1D population.

3.4.2.1.2 Dual Process Theory

As depicted by Social Cognitive Theory, knowledge is an important personal/cognitive determinant of behaviour (Bandura, 1997). People living with T1D require knowledge of the endocrine and metabolic response to physical activity so that appropriate strategies to manage blood glucose levels can be developed. The way this information is delivered to and received by the person living with diabetes is key to health-related behaviour change (Greenberg et al., 2018). Self-persuasion, as opposed to direct persuasion is thought to be more effective in inducing attitude change through information processing because in the case of self-persuasion, the individual *believes* they want to change rather than being *told* to change (Butler et al., 1996; Martin et al., 2005). Self-persuasion has been used successfully in education and behaviour change interventions for many years (Greenberg et al., 2018; Skinner et al., 2003; Wankel & Thompson, 1977).

A systematic view of persuasion was used throughout the delivery of Type 1 TACTICS for Exercise© to ensure participants were confident in their acquired knowledge and were equipped to scrutinise new information from external sources (Chaiken, 1980; Chaiken et al., 1996). Figure 3.4 shows the differences between systematic and heuristic processing in assessing message validity. Systematic processing requires greater cognitive effort as participants are asked to actively engage in the learning process and piece together information to draw their own conclusions (Chaiken et al., 1996). Heuristic processing, though easier for the participant, results in a superficial understanding of the information and results in opinions that are prone to change (Chaiken et al., 1996). The DESMOND collaborative discuss the use of self-persuasion and systematic processing in their diabetes self-management group education program with positive results; participants have been able to give detailed descriptions of the workshop up to a year after attending (Skinner et al., 2003). The use of Social Cognitive Theory and Dual Process Theory in Type 1 TACTICS for Exercise© is detailed in the following publication.

Figure 3.4

Dual Process Model: Heuristic Versus Systematic Processing
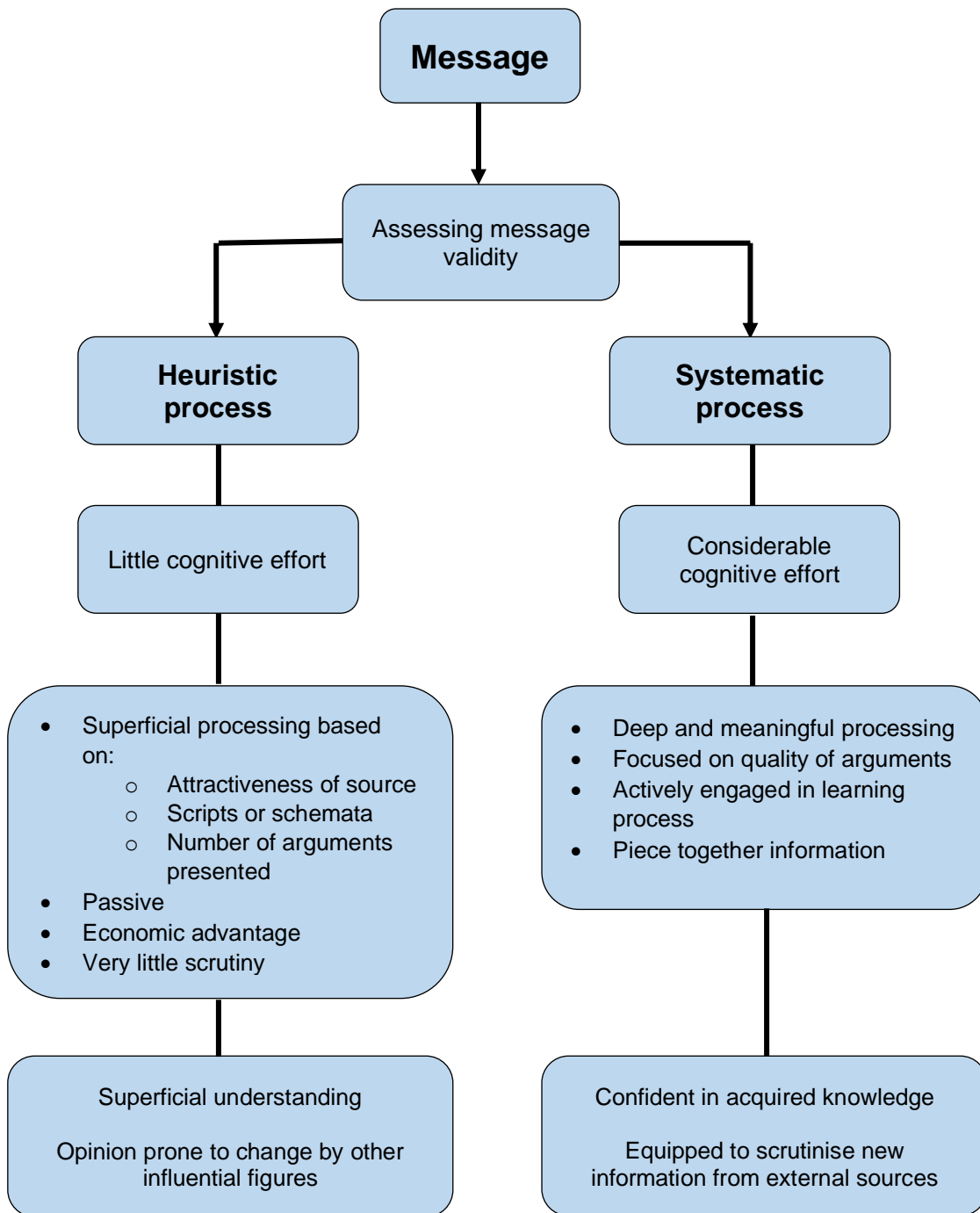
3.4.2.1.3   Behaviour Change Theories in Type 1 TACTICS for Exercise©

The following article describes how the aforementioned behaviour change theories underpinned Type 1 TACTICS for Exercise©, the intervention under investigation.

Brennan, M. C., Leslie, G. D., Ntoumanis, N., & Brown, J. A. (2021). Group self-management education to address fear of hypoglycaemia as a barrier to physical activity: The role of behaviour change theories. *Australian Diabetes Educator, 24*(1). https://ade.adea.com.au/group-self-management-education-to-address-fear-of-hypoglycaemia-as-a-barrier-to-physical-activity-the-role-of-behaviour-change-theories/

Australian
Diabetes
Educator

Volume 24, Number 1 - April 2021

Group self-management education to address fear of hypoglycaemia as a barrier to physical activity: The role of behaviour change theories.

Living With DiabetesOriginal Research

BY Marian C Brennan, Professor Gavin D Leslie, Professor Nikos Ntoumanis and Dr Janie A Brown

(empowerment) (life-skills) (type 1)

Introduction

Despite established physical activity (PA) guidelines and international consensus, [1] many people living with type 1 diabetes (T1D) are not currently meeting minimum PA requirements. Internationally, studies report between 65% to 82% of T1D study participants were not sufficiently active, [2,3] suggesting people with T1D may not be as active as their general population counterparts. [3,4,5,6,7] This disparity suggests there may be a difference in how people with T1D experience and approach PA. Blood glucose responses to PA in people with T1D can be extremely variable between and within individuals. The rate and direction of glucose excursions will depend on the intensity, type, duration, and timing of activity in relation to how much circulating insulin the individual has onboard. [1] These variables, as well as current blood glucose trends, will dictate how the individual adjusts their carbohydrate intake and/or insulin. [1,8] The

complex interplay between these variables makes T1D management very challenging before, during and up to 24 hours after PA, during which time hyper or hypoglycaemia can ensue. Indeed, our recent systematic scoping review found hypoglycaemia/fear of hypoglycaemia (FoH) were the most frequently described barriers to PA among adults living with T1D. [9] Despite the prevalence of hypoglycaemia/FoH as a barrier, there is a paucity of literature in how to address it. [9]

Current whole population PA campaigns are not equipped to address these unique challenges faced by the T1D population. [9] Without the knowledge, confidence, or specific self-management skills, it is conceivable that people living with T1D may choose to avoid PA to avoid the unpleasant and often unsafe extremes of hyper and hypoglycaemia. However, knowledge and skill alone are not suffice to change PA behaviour. [10] To encourage behaviour change, client education needs to be grounded in behaviour change theories that encourage psychosocial concepts such as self-efficacy and self-determined motivation. [10,11] Although theory-driven interventions have been shown to improve efficacy and are encouraged in key frameworks for developing behaviour change interventions, [12-14] our review found very few have trialled theory-driven PA diabetes education using robust study designs. [9]

In response, Type 1 TACTICS for Exercise©, a theory-driven, group self-management education program, was developed to address diabetes-specific barriers to PA, specifically FoH. We hypothesised that by addressing diabetes-specific barriers, people with T1D may be better equipped to participate in wider community PA initiatives alongside their counterparts living without T1D. We began investigating the practicality and need for this program in 2017 with a small explorative study. Early indications suggest the program may have some effect on FoH as a barrier to PA in a small group of adults with T1D and warranted further investigation following a number of program iterations. [15] In 2018, a larger and more robust investigation using a mixed methods RCT design was planned and piloted, the results of which have been published elsewhere. [16,17] The aim of this paper is to describe the intervention, Type 1 TACTICS for Exercise© and its underpinning theories, with reference to recently published participant outcomes. [16,17]

Type 1 TACTICS for Exercise©

Type 1 TACTICS for Exercise© was developed by Diabetes WA in 2017 in an effort to address a gap in services for adults living with T1D who experience diabetes-specific barriers to PA. The program consisted of an initial three-hour session, a one-hour booster session (four weeks following the initial session), and an optional private peer-led Facebook™ group. The program content detailed the endocrine and metabolic response to PA in T1D; how intensity, type, timing, frequency, and duration of activity effects blood glucose response; contemporary evidence-informed strategies to manage blood glucose levels for PA (as per Riddell et al. [1] consensus statement); and encouraged participants to problem solve their own exercise scenarios as a group. Two validated and widely used psychological learning theories, Dual Process Theory [18] and Social Cognitive Theory [19], underpinned the program and guided its delivery.

The role of Dual Process Theory

Dual Process Theory, or more specifically, the heuristic-systematic model of information processing distinguishes between heuristic and systematic processing. [18] Heuristic processing is a passive form of persuasion by which a participant relies on simple rules or cognitive heuristics and is likely to agree with messages delivered by 'experts' without meaningfully scrutinising its content. [20] This form of information processing can result in superficial understanding and opinion change, prone to subsequent change by other influential figures within family, social circles, or the media. [21] This can create confusion and frustration for the person living with diabetes.

To encourage meaningful information processing, we delivered education relating to the endocrine and metabolic response to PA using systematic processing. Systematic processing requires participants to actively engage in the learning process by scrutinising and piecing together information. Unlike heuristic processing, the facilitator guides participants' knowledge discovery, giving as little information as possible. [18,21] Visual aids (Feltman® [22]), analogies, and careful questioning by the facilitator helped participants to understand how intensity, type, timing, frequency, and duration of activity effects blood glucose response. For example, the concept of muscle contraction-mediated glucose uptake (insulin-independent pathway) was explained using the analogy of 'magic doors' (that is, doors on a muscle cell that are wide open without relying on insulin to open the door) appearing on the muscle cell with muscle contraction. Once participants understood fundamental principles of how their body responds to activity, they were able to deduce which management strategies and *tactics* to employ to minimise variation in blood glucose levels. They were able to

take new information away to explore and test it in their day-to-day T1D management. Systematic processing allows participants to be more confident in their acquired knowledge, so they are equipped to scrutinise new information from external sources. [21] Similar to the experiences of others using systematic processing in diabetes education, we found participants' recall of this information was excellent up to six months after the intervention. [17, 21]

The role of Social Cognitive Theory

Social Cognitive Theory explains that individuals learn by observing others and this experience will be influenced by personal factors, environmental factors and behaviour. [19] The reproduction of observed behaviour is reliant on a person's belief in their ability to complete the behaviour – self-efficacy.19 Self-efficacy is a key determinant of health behaviours, both directly and indirectly. [23] Bandura [19] outlines four key sources of self-efficacy: mastery experience, role modelling, verbal persuasion, and physiological and affective states. [24] Type 1 TACTICS for Exercise© was delivered in a group environment by an experienced and skilled facilitator who exposed participants to these key sources of self-efficacy in an effort to reduce barriers to PA.

The most influential source of self-efficacy is mastery experience and was a key focus of the intervention. [25] Type 1 TACTICS for Exercise© created opportunities for participants to gain self-efficacy belief from their own experiences both during and after the intervention. Participants were encouraged to plan out personal PA scenarios using the 'timeline activity' and problem solve anticipated or experienced problems with the new skills and tactics they had learnt. Participants had the opportunity to trial these plans with the support of a peer-led Facebook™ group over four weeks and returned to the booster session to discuss their experiences and learnings.

Role modelling was a dominant feature of the intervention. Participants were encouraged to gain self-efficacy belief from the success of others by observing their blood glucose management with PA then applying these learnt strategies. Role modelling was also fostered by the Facebook™ group, where participants were encouraged to share their experiences and ask questions of their peers. The T1D-specific group setting cultivated this source of self-efficacy as individuals are more likely to model behaviours from people with whom they identify. [25]

Although less powerful than mastery experience and role modelling, positive verbal persuasion was used by both the facilitator and participants as another means of improving self-efficacy. [19] Positive behaviours and efforts were encouraged by the group during face-to-face encounters and Facebook™ group interactions. For example, when a participant shared their successes or challenges with the group, they were met with encouragement, support, and ideas of how to move forward.

Physiological and affective states were also explored with participants. These states are important as some individuals may interpret negative emotions or bodily symptoms as a sign of incapability. [26] For example, an individuals' experience of FoH as a barrier to PA may be attributed to being personally incapable of managing hypoglycaemia, rather than to a changeable physiological state. Exploration of this barrier from a physiological and affective state helped participants to correctly attribute negative emotions and bodily symptoms. This may help reduce fear by allowing participants to focus on active strategies to manage blood glucose for PA.

Discussion

Although it is common to see key frameworks encourage theory-driven behaviour change interventions, few have been trialled in the area of PA for T1D. [12-14] We trialled the use of Dual Process Theory [18] and Social Cognitive Theory [19] to facilitate a group self-management education program with the aim to address FoH as a barrier to PA in adults living with T1D in Perth, Western Australia. In order to evaluate the feasibility, acceptability, and preliminary efficacy of this theory-driven group education program, we conducted a single blind RCT and focus group interviews with adults living with T1D in Perth, Western Australia. Preliminary efficacy, supported by qualitative findings suggest learning using systematic processing, mastery experience, role modelling, verbal persuasion, and exploring physiological and affective states may lead to improved self-efficacy to manage blood glucose levels with PA and a reduction in barriers to PA, (including FoH). [16] A full discussion of our study results has been published and reported elsewhere. [16, 17] A future definitive trial is justified to replicate preliminary efficacy and to determine the utility of Type 1 TACTICS for Exercise© in improving PA participation. Local dissemination of Type 1 TACTICS for Exercise© will occur in parallel with this trial in an effort to pilot new program iterations, resources, and facilitator training models.

Conclusion

Providing education on blood glucose management for PA to adults living with T1D is challenging owing to complex diabetes-specific barriers to PA. In order to assist those experiencing these barriers, diabetes health professionals need to consider theory-driven approaches to behaviour change. Facilitating an opportunity for group education and/or interactions for those living with T1D appears to be an important feature in addressing diabetes-specific barriers to PA. Behaviour change theories that encourage systematic learning and self-efficacy through mastery experience and role modelling from relatable peers are key to PA behaviour change in this population. Where group interactions are not possible, diabetes health professionals should focus on improving self-efficacy through mastery experience – learning from their own experiences and guided trial and error.

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3.4.2.2   Behaviour Change Techniques

While behaviour change theories provide causal determinants of behaviour and provide a degree of specification as to the why and how of behaviour change, there is often no guidance on specific techniques that should be used to change behaviour (Ajzen, 2019; Bohlen et al., 2020). Behaviour change techniques are "observable, replicable, and irreducible component(s) of an intervention designed to alter or redirect causal processes that regulate behaviour" (Michie et al., 2013, p. 82); they are the "active ingredients" within an intervention (Michie & Johnston, 2012; Michie et al., 2013). Behaviour change interventions typically use multiple BCTs, though more BCTs do not always result in greater efficacy (Bohlen et al., 2020; Dombrowski et al., 2012; Prestwich et al., 2014). Intervention effectiveness is, however, associated with the use of BCTs that align with a behaviour change theory (Dombrowski et al., 2012; Prestwich et al., 2014). For example, *behaviour practice/rehearsal*, *demonstration of the behaviour* and *instruction on how to perform the behaviour* are BCTs linked with Social Cognitive Theory as agreed upon by expert consensus and literature synthesis (Bohlen et al., 2020), and feature in Type 1 TACTICS for Exercise[©]. A comprehensive taxonomy of 93 distinct BCTs (BCT Taxonomy v1) was used by the candidate (trained online, www.bct-taxonomy.com) post-hoc to systematically map BCTs evident in the Type 1 TACTICs for Exercise[©] facilitator manual (Michie et al., 2013) (Table 3.3). Budget constraints prohibited independent BCT mapping, however an experienced member of the candidate's supervision team (NN) reviewed this assessment to mitigate any bias. Type 1 TACTICS for Exercise[©] was a pre-existing

intervention and behaviour change techniques were not selected prior to intervention development, however post-hoc mapping revealed all crucial BCTs for the target behaviours were included (Michie et al., 2013). Independent BCT coding was not included in fidelity coding described in section 4.2 as the coder was not experienced in coding BCTs.

3.5   Data Collection Tools for Efficacy

The choice of data collection tools was guided by primary and secondary objectives which were shaped by the findings of the systematic scoping review in Section 2.2 (Brennan, Brown, Ntoumanis, et al., 2021). By addressing the main barriers to physical activity identified in the systematic scoping review – hypoglycaemia, FoH, and psychosocial factors (embarrassment/discouragement to engage in physical activity by those around them; low confidence/overwhelmed by managing blood glucose levels for physical activity; diabetes distress; depression) – people with T1D may be better placed to engage in wider community physical activity initiatives. As such, changes to barriers to physical activity, self-efficacy (in blood glucose management and physical activity participation), attitudes and intentions towards physical activity, self-reported physical activity, diabetes distress, and well-being were included as either primary or secondary outcomes (Table 3.1). Data collection methods relating to feasibility and acceptability aspects are detailed in publications presented in Chapter 4.

3.5.1   Barriers to Physical Activity

People living with T1D experience unique barriers to physical activity that need to be addressed before improvements can be expected in physical activity participation in this population (Brennan, Brown, Ntoumanis, et al., 2021). Barriers to physical activity in adults living with T1D are significantly associated with physical activity energy expenditure (r^2=0.06, p=0.03), physical activity level (r=-0.24, p=0,03), and HbA1c (r=0.2, p=0.04) (Brazeau et al., 2012; Brazeau et al., 2008). It was hypothesised that once diabetes-specific barriers to physical activity are addressed, individuals will be better placed to receive aspects of physical activity behaviour change interventions, hence barriers to physical activity were chosen as a key outcome in the pilot RCT. Identified as the most common barrier to physical activity among adults living with T1D (Brennan, Brown, Ntoumanis, et al., 2021), reducing FoH as a barrier was chosen as a primary outcome measure.

Barriers to physical activity were measured at t_1, t_2, and t_3 using the Barriers to Physical Activity in Diabetes – type 1 (BAPAD1) scale (Dubé et al., 2006). The BAPAD1 is an 11-item, 7-point Likert scale, first developed in 2006. Content validity was determined by professional subjective judgement by two experts in the field of physical activity and diabetes. The scale showed sound psychometric properties with a Cronbach alpha coefficient of 0.85 and test-retest correlation scores of 0.84. An item of particular interest was item 2, the risk of hypoglycaemia (referred to as 'fear of hypoglycaemia' by (Brazeau et al., 2008) which scored an item-total correlation of 0.67 (Dubé et al., 2006). The BAPAD1 is the only tool to provide validated measurement of barriers to physical activity in this target population. Thresholds for clinical significance have not been defined for this tool.

Although other measures of FoH exist (Gonder-Frederick et al., 2011; Polonsky et al., 2020), all are measures of FoH across all aspects of management and daily living. These measures may have lacked specificity to FoH experienced as a barrier to physical activity. For example, a participant may experience a reduction in FoH as a barrier to physical activity as a result of the intervention (as this is what the intervention aimed to target) but may still experience generalised FoH in other aspects of diabetes management. The opposite may also be true for participants. In the absence of a more specific tool, the BAPAD1 was deemed the most suitable measure of FoH as a barrier to physical activity.

3.5.2 Self-Efficacy

Perceived self-efficacy is a person's belief in their capability to perform a particular behaviour to achieve performance goals and can influence motivation, thought, affect, and action (Bandura, 1977, 2006). As it was not feasible to include objective device-driven measures of physical activity in the pilot trial, it was important to measure determinants and predictors of activity to gauge the interventions potential to change physical activity behaviour.

Although many self-efficacy scales specific to diabetes management exist, specific tools for physical activity in T1D have not been developed or assessed for validity and reliability. As such, two self-efficacy scales were developed using Bandura's guide for constructing self-efficacy scales (Bandura, 2006): Self-efficacy in managing blood glucose levels before, during, and after physical activity; and self-efficacy in participating in 30-minutes of physical activity, five days per week (Appendix B – Supplementary Appendix 1, Questions 40-42 and 32-35, respectively). Self-efficacy across these domains was measured at t_1, t_2, and t_3. Self-efficacy to manage blood glucose levels before, during, and

after physical activity was measured using a 100-point scale, ranging in 10-unit intervals from 0 (cannot do), through intermediate degrees of assurance at 50 (moderately certain can do), to complete assurance at 100 (highly certain can do) (Bandura, 2006). Self-efficacy to participate in 30-minutes of physical activity, five days per week was measured across three items using a 7-point Likert scale. Internal reliability (α) was measured using Cronbach's alpha as per Bandura's guide (Bandura, 2006) and was 0.79 (0.67, 0.86) for items relating to self-efficacy in physical activity participation. Constructs with a Cronbach's alpha of <0.7 were excluded from analysis. Pre-determined benchmarks are not available for these measures of self-efficacy.

3.5.3 Attitudes and Intentions Towards Physical Activity

Attitude is central to predict and explain behaviour (Fishbein & Ajzen, 2010). Attitude is defined as a "tendency to respond with some degree of favourableness or unfavourableness to a psychological object" (Fishbein & Ajzen, 2010, p. 76). Prior to actual behaviour change, there is an intention to pursue an action. Intention is a person's readiness to perform a behaviour (Fishbein & Ajzen, 2010). The higher the person's estimate of the likelihood of performing a given behaviour, the more likely that behaviour will be performed (Fishbein & Ajzen, 2010). Like self-efficacy, measures of attitudes and intentions towards physical activity were deemed necessary in the absence of objective device-driven measures of physical activity.

Specific tools to measure attitude and intentions towards physical activity in T1D have not been developed or assessed for validity and reliability in the T1D population. As such, a measure of attitudes and intentions towards physical activity in adults living with T1D was developed using the guidance of Fishbein and Ajzen (2010). The tool included four, 7-point Likert scale items for the construct, attitudes towards physical activity (Appendix B – Supplementary Appendix 1, Questions 24-27), and three questions, 7-point Likert scale items for the construct, intentions towards physical activity (Appendix B – Supplementary Appendix 1, Questions 36-38). These outcomes were measured at t_1, t_2, and t_3. Internal reliability was measured using Cronbach's alpha and constructs with a score of <0.7 were removed from the analysis. Cronbach's alpha for attitude items was 0.8 (0.73, 0.86) and 0.89 (0.80, 0.94) for the construct of intention. Pre-determined benchmarks are not available for these measures of attitudes and intentions.

3.5.4 Self-Reported Physical Activity

It was not feasible to use objective device-driven measures of physical activity due to research budget constraints. The study used the International Physical Activity Questionnaire – Short Form (IPAQ-SF) at t_1, t_2, and t_3 to gauge preliminary effects of the intervention on self-reported physical activity (Craig et al., 2003). Physical activity was not a primary outcome of this pilot trial. It was essential to first, establish if the intervention was feasible, acceptable, and potentially effective in reducing prominent diabetes-specific barriers to physical activity. Physical activity participation is a clinically important measure for future trials determining the utility of the intervention (if found to be feasible and acceptable) in physical activity behaviour change given its association with improved health outcomes for this population (Bohn et al., 2015; Chimen et al., 2012; Moy et al., 1993; Tielemans et al., 2013; Wadén et al., 2008; Yardley et al., 2014).

The IPAQ-SF is a 6-item questionnaire that assesses physical activity across moderate intensity, vigorous intensity, and walking; frequency; and duration. The IPAQ-SF has been shown as a reliable measure of physical activity across numerous countries, with 75% of the test-retest Spearman's reliability coefficients observed above 0.65 (Craig et al., 2003). The criterion validity of the IPAQ-SF against Computer Science and Application's Inc. (Shalimar, FL) accelerometers is fair to moderate (p=0.30, 95% CI 0.23-0.36) and comparable to other established self-reports (Craig et al., 2003). The short form was chosen as it is generally better received than the long form version, reducing responder fatigue (Craig et al., 2003).

3.5.5 Diabetes Distress

In the general population, psychological distress (symptoms of anxiety, depression, and other indices of distress that affect functional abilities) is associated with lower levels of physical activity and vice versa (Gucciardi et al., 2020). A specific form of psychological distress related to the emotional burden, worry, and stress associated with managing diabetes is known as *diabetes distress* (Fisher et al., 2014). People living with T1D report ongoing fear of future diabetes-related complications, and social and psychological burdens, long after they have been diagnosed with the condition (Skovlund & Peyrot, 2005). Managing blood glucose levels for physical activity can be very complicated and has the potential to add to the burden of living with T1D (Michael C. Riddell et al., 2017), so tracking diabetes distress throughout the pilot RCT was important. Diabetes distress was also identified as a common barrier to physical activity (Brennan, Brown, Ntoumanis, et al., 2021), further substantiating its inclusion as an outcome (measured at t_1, t_2, and t_3).

The Problem Areas in Diabetes Scale (PAID) - Short Form is a widely used, 5-item scale to measure diabetes distress. The PAID-5 has been validated in numerous contexts and used as an outcome measure in research trials. It displayed sound reliability across two sub-samples, Cronbach's alpha (95% CI) of 0.86 (0.84-0.88) and 0.83 (0.8-0.85) (McGuire et al., 2009). The validity of the PAID-5 has been demonstrated by a statistically significant correlation with the World Health Organisation Well-being Index – 5 (WHO-5), a measure of well-being (r=-0.47, p<0.001). The PAID-5 correlates well with the PAID-20, the full 20-item version of this scale (r=0.92, p<0.001) (McGuire et al., 2009) and was chosen over the PAID-20 to lessen responder fatigue. Benchmarks for meaningful change in the PAID-5 score do not exist.

3.5.6   Well-Being

Almost half of all people with diabetes in the Diabetes Attitudes, Wishes, and Needs (DAWN) study experienced poor well-being (Skovlund & Peyrot, 2005). Psychological well-being has been described by participants of the Diabetes Management and Impact for Long-term Empowerment and Success 2 (MILES-2) survey in Australia, as the aspect of life most negatively impacted by T1D (Ventura et al., 2016). Like diabetes distress, poor psychological well-being can negatively affect diabetes outcomes and an individual's ability to effectively manage their condition and engage in physical activity (Brennan, Brown, Ntoumanis, et al., 2021; Peyrot et al., 2005; Skovlund & Peyrot, 2005). As such, the effect of the intervention on psychological well-being was included as an outcome and measured at t_1, t_2, and t_3.

The 5-item, 6-point Likert scale WHO-5 is one of the most widely used questionnaires to assess psychological well-being (Topp et al., 2015). It displays sound psychometric properties as a clinical and outcome measure, particularly in the diabetes population. The WHO-5 has been shown to possess a weighted sensitivity of 0.86 and specificity of 0.81 for the diagnosis of depression across various clinical populations (Topp et al., 2015). It has consistently captured changes in well-being caused by various non-pharmacological interventions in trials across many clinical cohorts, including T1D in Australia (Halliday et al., 2017; Topp et al., 2015). The benchmark for clinical significance is a change of 10 points on the WHO-5 (Topp et al., 2015).

3.6   Ethics

Potential ethical challenges were considered and protocols established to ensure ethical conduct throughout the study (National Health and Medical Research Council, 2007b). These included:

- Written permission from Diabetes WA® to undertake the study (Appendix D.5).

- Diabetes WA® database registrants opting for 'do not contact for research' were not sent details of the research.

- The participant information statements and verbal statements provided details of the project, expected benefits risks, and inconveniences, privacy and data management, and informed participants that they were able to withdraw at any time without jeopardising their relationship with the University or Diabetes WA® (Appendix D.9).

- Written consent via a Qualtrics™ link was sought before randomisation, completion of questionnaires, recording sessions, and participation in focus groups (Appendix D.10).

- Participants were given the option to withdraw from the study if they did not consent.

- Participants were encouraged to contact the PhD candidate (M.B) or Diabetes WA® helpline if they felt overwhelmed, distressed, or experienced negative changes in mood during the course of the study.

- In the event of disclosed distress or low mood, referral to appropriate support services would have been arranged with the participant's permission.

- All participants had unfettered access to resources and support from Diabetes WA® during the course of the study and were free to consult with their personal diabetes health professionals.

- Participants randomised to the control arm received information regarding physical activity so as not to conceal the benefits of activity to this population.

- Given physical activity can increase the risk of hypoglycaemia in those living with T1D (Frier, 2008), the control arm also received a review of hypoglycaemia

management procedures to ensure confidence and competency in this area. Those allocated to the intervention were exposed to the same baseline information.

- Participants randomised to the control were given the opportunity to attend the intervention at the conclusion of the study.

- All data was coded and deidentified and will be stored for a minimum of 25 years and then destroyed as per the national guidelines (National Health and Medical Research Council, 2007a) and the research data management plan (Appendix D.11).

Human Research Ethics Committee approval was obtained through Curtin University (HRE2018-0795 – Appendix D.6) and State Health Service HREC (RGS0000003164 – Appendix D.7), as per the national guidelines (National Health and Medical Research Council, 2007b). The quantitative pilot RCT component of this study was registered with the Australian New Zealand Clinical Trials Registry ACTRN12618001729213p (www.anzctr.org.au). Any protocol modifications were sent as amendments to the University HREC, State Health Service HREC and the Australian New Zealand Clinical Trials Registry.

The following amendments were approved by Curtin HREC:

15th February 2019 – Amendment approval number HRE2018-0795-02 (Appendix D.8.1)

- Addition of consent form for randomisation

- Addition of pregnancy as an exclusion criterion

- Addition of questions within existing questionnaires at $t_1 – t_3$

18th April 2019 – Amendment approval number HRE2018-0795-04 (Appendix D.8.2)

- Addition of four new images to be used in recruitment

1st May 2019 – Amendment approval number HRE2018-0795-06 (Appendix D.8.3)

- Expansion of recruitment area from Perth metropolitan only, to Bunbury/Busselton and surrounds

- Interviewing a willing project steering group member with T1D to share his journey of T1D and physical activity – to be used in local newspapers to raise awareness of study

16th September 2019 – Amendment approval number HRE2018-0795-08 (Appendix D.8.4)

- Update details of semi-structured focus group schedule

- Demographic questionnaire for focus group participants

Chapter 4   Results

Discrete quantitative and qualitative methods and results were reported in two separate publications (Brennan, Albrecht, et al., 2021; Brennan, Brown, Leslie, et al., 2021). The first results publication presented in Section 4.1 reports quantitative methods and findings relating to the feasibility and acceptability of procedures of the pilot RCT, as well as preliminary efficacy of the intervention on FoH as a barrier to physical activity and associated secondary outcomes (Brennan, Albrecht, et al., 2021). The second results publication presented in Section 4.2 is a process evaluation of the study procedures, the intervention, and the control (Brennan, Brown, Leslie, et al., 2021). It reports methods and results of the focus group interviews, the use and helpfulness of intervention resources, Facebook™ data, and fidelity coding, all used to inform broader aspects of acceptability of study resources and procedures.

4.1 Quantitative Assessment of Feasibility, Acceptability, and Preliminary Efficacy

Brennan, M. C., Albrecht, M. A., Brown, J. A., Leslie, G. D., & Ntoumanis, N. (2021). Self-management group education to reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes: A pilot randomised controlled trial. *Canadian Journal of Diabetes, S1499-2671(21)00001-0. Advance online publication.* https://doi.org/10.1016/j.jcjd.2021.01.001

Original Research

Self-Management Group Education to Reduce Fear of Hypoglycemia as a Barrier to Physical Activity in Adults Living With Type 1 Diabetes: A Pilot Randomized Controlled Trial

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Key Messages

- Very few interventions targeting fear of hypoglycaemia (FoH) as a barrier to physical activity (PA) have been trialled, despite its prominence as a barrier.
- A pilot RCT of a self-management group education intervention designed to address FoH as a barrier to PA is acceptable to adults with T1D and feasible to deliver.
- Adjunct components to facilitate PA behaviour change among inactive individuals with T1D are required.

ABSTRACT

Objectives: The aim of this study was to evaluate the feasibility, acceptability and preliminary efficacy of a theory-driven group education intervention designed to reduce fear of hypoglycemia (FoH) as a barrier to physical activity (PA) in adults with type 1 diabetes (T1D).
Methods: This study was a single-blinded, pilot randomized controlled trial of adults aged 18 to 65 years and living with T1D in Western Australia. Participants were randomized (1:1) to standard care or intervention with self-management education. Primary outcomes were feasibility and acceptability of the study procedures, and change to barriers to PA and FoH. Secondary outcomes were change to attitudes and intentions toward PA, self-reported participation in PA, self-efficacy, diabetes distress and well-being. To calculate effect sizes, we used a Bayesian comparison of the between-group difference scores (i.e. [$score_{t2} - score_{t1}$]$_{TREATMENT}$ vs [$score_{t2} - score_{t1}$]$_{CONTROL}$).
Results: We randomized 117 participants with T1D, 86 (74%) of whom provided baseline data and attended initial workshops. Of these participants, 81% attended the booster workshop 4 weeks later. They were 45±12 years of age, reported high levels of activity and had been living with T1D for 20±14 years. Small-to-moderate effect sizes [ESs] in favour of the intervention were observed at 12 weeks for overall barriers to PA (ES, −0.38; highest density interval, −0.92 to 0.17), self-efficacy for blood glucose management after PA (ES, 0.45; highest density interval, 0 to 0.91), diabetes distress (ES, −0.29; highest density interval, −0.77 to 0.15) and well-being (ES, 0.36; highest density interval, −0.12 to 0.8).

Conclusions: Quantitative findings indicate study procedures were acceptable to participants and feasible to deliver. A future definitive trial is justified to replicate preliminary efficacy and to determine the utility of the intervention for improving PA participation.

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R É S U M É

Objectifs : L'objectif de la présente étude était d'évaluer la faisabilité, l'acceptabilité et l'efficacité préliminaire d'une intervention d'éducation de groupe fondée sur la théorie conçue pour atténuer la crainte de l'hypoglycémie (CdH), qui est considérée comme un obstacle à l'activité physique (AP) chez les adultes atteints du diabète de type 1 (DT1).

Méthodes : Il s'agissait d'un essai comparatif pilote à répartition aléatoire en simple insu auprès d'adultes de l'Australie-Occidentale qui étaient âgés de 18 à 65 ans et atteints du DT1. Nous avons réparti de façon aléatoire (1:1) les participants aux soins courants ou à l'intervention d'éducation à la prise en charge autonome. Les principaux critères d'évaluation étaient la faisabilité et l'acceptabilité des procédures de l'étude, et les changements concernant les obstacles à l'AP et la CdH. Les critères d'évaluation secondaires étaient les changements concernant les attitudes et les intentions à l'égard de l'AP, la participation autodéclarée à l'AP, l'auto-efficacité, la détresse liée au diabète et le bien-être. Pour le calcul des tailles d'effet, nous avons utilisé l'approche bayésienne pour comparer les scores de différences entre les groupes (c.-à-d. THÉRAPIE [score$_{t2}$ − score$_{t1}$] *vs* TÉMOIN [score$_{t2}$ − score$_{t1}$]).

Résultats : Nous avons réparti de façon aléatoire 117 participants atteints du DT1, dont 86 (74 %) d'entre eux avaient fourni des données initiales et avaient participé aux premiers ateliers. Parmi ces participants, 81 % ont participé à l'atelier d'appoint 4 semaines plus tard. Ils étaient âgés de 45 ± 12 ans, déclaraient des niveaux d'activité élevés et vivaient avec le DT1 depuis 20 ± 14 années. Nous avons observé des tailles d'effet [TE], de petites à modérées, favorables à l'intervention après 12 semaines pour l'ensemble des obstacles à l'AP (TE, −0,38; intervalle HPD [de l'anglais, *highest density interval*], de −0,92 à 0,17]), l'auto-efficacité de la prise en charge de la glycémie après l'AP (TE, 0,45; intervalle HPD, de 0 à 0,91]), la détresse liée au diabète (TE, −0,29; intervalle HPD, de −0,77 à 0,15) et le bien-être (TE, 0,36; intervalle HPD, de −0,12 à 0,8).

Conclusions : Les résultats quantitatifs indiquent que les procédures de l'étude étaient acceptables pour les participants et réalisables. Une étude définitive future en vue de reproduire l'efficacité préliminaire et de déterminer l'utilité de l'intervention à l'amélioration de la participation à l'AP est justifiée.

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Introduction

Daily management of type 1 diabetes (T1D) seeks to minimize hyper- and hypoglycemic events, and reduce the risk of long-term diabetes-related complications (1). Although the principal treatment for T1D is lifelong exogenous insulin, adjunct management strategies include carbohydrate adjustment to maintain euglycemia and physical activity (PA) (1,2). PA is an important feature of T1D management, improving cardiovascular health, reducing required insulin dose and possibly improving glycated hemoglobin (A1C) levels (3). To achieve these benefits, it is recommended that those living with T1D engage in at least 150 minutes of moderate-intensity PA per week and resistance training 2 days/week, while limiting sitting time (4). Despite these recommendations, it has been reported that between 65% and 83% of those with T1D do not meet PA guidelines in Australia, Austria, Germany, Canada and the United States (5–8).

People with T1D report barriers to PA that parallel those experienced by the wider population, but "diabetes-specific" barriers are reported most frequently (9). Hypoglycemia and fear of hypoglycemia (FoH) are the most frequently cited reasons for inactivity. Very few interventions targeting diabetes-specific barriers to PA participation in T1D have been trialled, and even fewer have been grounded in behaviour change theory (10–12). Most trials to date have focused on PA, maximum rate of oxygen consumption and/or A1C as key outcomes (10–13), with many yet to identify effective methods to improve long-term PA participation.

Theory-driven interventions designed to address and measure changes to diabetes-specific barriers are needed to understand what is required to change PA behaviour in the T1D population. Interventions underpinned by theory can help identify how and why behaviour change occurs, under what circumstances and for whom (14). Type 1 Tactics for Exercise is a theory-driven self-management group education program designed to address diabetes-specific barriers to PA, including FoH. Group education was chosen to encourage peer interaction and support, which are likely to nurture self-efficacy through role modelling and verbal persuasion—2 key sources of self-efficacy (15). Our aim was to evaluate the feasibility, acceptability and preliminary efficacy of this intervention for adults with T1D using a mixed-methods, pilot randomized controlled trial (RCT). We report our quantitative findings relating to the following objectives:

- Assessing feasibility and acceptability of procedures across the study schedule.
- Examining potential effects of the intervention on FoH as a barrier to PA and associated secondary outcomes.

Methods

Trial design

The design of this pilot RCT was guided by the 2010 CONSORT Statement: Extension to Randomised Pilot and Feasibility Trials

(16). The investigation was informed by a previous exploratory, nonrandomized, pre/post study design. It was suggested that Type 1 Tactics for Exercise could reduce FoH as a barrier to PA in a small sample of adults with T1D, and showed sufficient promise to warrant further program iterations as well as more extensive and robust investigation (17). A steering group comprising T1D consumers, diabetes educators, clinicians and representatives from local and national diabetes bodies guided this study. Participants were blinded and randomized into 1 of 2 parallel groups, either a standard care (control) group or a Type 1 Tactics for Exercise workshop (intervention) group, and attended sessions at regional and metropolitan locations in Western Australia. The complete study schedule is shown in Table 1. Study approval was obtained through Curtin University (HRE2018-0795) and the human research ethics committee of the State Health Service (RGS000 0003164). The investigation was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12618001729213p).

Sample size

As the key objectives of this pilot RCT included testing trial acceptability and intervention procedures, a sample size calculation was not performed (16). We anticipated the effects size for the primary outcome to be small; therefore, using stepped rules of thumb (proposed sample sizes depending on whether the standardized effect size for the main trial is extra small, small, medium or large), a target sample of 100 participants was proposed (18). Although individual group sizes of 5 to 7 are considered optimal for group education, a pragmatic decision was made to set group size limits at between 2 and 12 participants to avoid excessive rescheduling and subsequent dropout (19,20).

Recruitment and participants

Study recruitment was open between February and September 2019 (Table 1). We advertised on media platforms of the top diabetes organization in Western Australia and distributed 3 mass e-mails to potential participants 18 to 65 years of age and with a diagnosis of T1D, who were living in or near Perth, Western Australia. Various hospital diabetes clinics, primary health and private practice clinics displayed study posters and pamphlets. Expressions of interest were directed to the research team for further explanation of the study and to administer screening questions and obtain written consent.

Participants 18 to 65 years of age, who had been diagnosed with T1D for >6 months, were proficient in English and willing to attend an initial and booster workshop, were eligible to participate in the study. Individuals were excluded if they reported:

- Significant complications of diabetes (or other medical conditions) precluding PA (e.g. vitreous hemorrhage).
- Pregnancy.
- Participation in the 2017 explorative study.

If medical eligibility was not clear, the participant was asked to seek medical clearance from their treating doctor.

Randomization

Eligible and consented participants were randomized using a computer-generated random allocation sequence (Randomizer for Clinical Trials, Medsharing SARL, 2020). The sequence was concealed by the computer program until assignment. Single-blinded block randomization was used to balance intervention and control arms, using a block size of 8 with a 1:1 allocation. Participants were informed they would receive 1 of 2 forms of group education, but they were not told which was the intervention or control. Allocations remained concealed from participants until all data collection had been completed. We were unable to blind the research team because the same researcher managed recruitment, screening, randomization, intervention/control delivery and data collection.

Table 1
Study schedule

	Study schedule				
	Enrolment and allocation at t_0	Postallocation			
		t_1	t_2	t_3	t_4
Enrolment					
Eligibility screen	X				
Informed consent	X				
Allocation	X				
Workshops					
Intervention−initial		X			
Intervention−booster			X		
Intervention Facebook group		●——————————————————————→			
Control−initial		X			
Control−booster			X		
Assessments (both study arms): Questionnaire		X	X	X	
Barriers to PA (BAPAD1 scale)					
Confidence−PA + BGL for PA (24)					
Attitudes and intentions−PA (25)					
Activity level (IPAQ-SF)					
Diabetes distress (PAID-SF)					
Well-being (WHO-5)					
Self-reported hypoglycemia					
Focus group					X

BAPAD1, Barriers to Physical Activity in Diabetes−Type 1 (23); *BGL*, blood glucose level; *IPAQ-SF*, International Physical Activity Questionnaire−Short Form (26); *PA*, physical activity; *PAID-SF*, Problem Areas In Diabetes−Short Form (40); t_0, over a 7-month period, allocation within 1 week of enrolment; t_1, within 1 month of enrolment; t_2, 4 weeks post-t_1; t_3, 8 weeks post-t_2; t_4, within 1 month of t_3; *WHO-5*, 5-item World Health Organization Well-Being Index (28).

Table 2
Type 1 Tactics for Exercise program summary

Section	Content	Theory in action	Behaviour change techniques *
Type 1 TACTICS for Exercise–initial session			
Section 1: Introduction, housekeeping and program overview	• Questions • Current PA recommendations • Barriers to PA • Program overview	• Skills mastery—self-reflection	1.2; 5.1; 6.2
Section 2: Carbohydrate metabolism	• Metabolic and endocrine response to PA in people with and without T1D	• Systematic processing • Open discovery questions • Skills mastery—self-reflection • Physical and psychological affect • Verbal persuasion	5.1; 6.2; 16.3
Section 3: Preparing for exercise	• Planning for PA • Contraindications/consider-ations for PA	• Verbal persuasion • Skills mastery—self-reflection	11.3; 16.3
Section 4: BGLs	• Monitoring BGL • Targets • Introduce the "timeline activity"	• Verbal persuasion • Skills mastery—self-reflection	6.2; 8.6; 11.3; 15.3; 16.3
Section 5: Carbohydrate intake	• Recommended carbohydrate intake for PA • Build timeline activity to include carbohydrates	• Skills mastery • Role modelling • Skills mastery	4.1; 4.2; 6.1; 6.2; 8.1; 8.7; 9.3; 11.3; 15.3; 16.3
Section 6: Insulin	• Insulin pharmacokinetics • Use timeline activity to explore the effect of bolus insulin • Basal insulin	• Skills mastery • Role modelling • Skills mastery	4.1; 4.2; 6.1; 6.2; 8.1; 8.7; 9.3; 11.3; 15.3; 16.3
Summary	• Exercise diary • Facebook support group and/or e-mail contact • Review key messages • Reflection	• Verbal persuasion • Skills mastery	2.3; 3.1; 3.3; 4.2; 5.4
Goal setting	• My Action Plan worksheet	• Verbal persuasion • Role modelling	1.1; 1.2; 1.3; 1.4; 15.1
Type 1 Tactics for Exercise—booster session			
Section 1: Introduction	• Welcome participants back • Ask group about their goals from 4 weeks ago • Questions	• Verbal persuasion • Role modelling—sharing obstacles	5.4; 6.2; 15.1
Section 2: Scenarios	• Discuss PA scenarios • Work through scenarios from last 4 weeks	• Skills mastery • Verbal persuasion • Physical and emotional Management	3.1; 3.3; 4.2; 5.4; 6.1; 6.2; 8.1; 11.3; 15.3; 16.3
Section 3: Conclusions	• Revisit barriers to PA from 4 weeks ago • Revisit burning questions from 4 weeks ago • Revisit goal setting	• Role modelling • Verbal persuasion • Skills mastery	1.1; 1.2; 1.3; 1.4; 2.3; 3.1; 3.3; 4.2; 8.7; 15.1

BGL, blood glucose level; PA, physical activity; T1D, type 1 diabetes.
Note: Full version of program summary available in Supplementary Appendix 1.
* Coded using the Behavior Change Technique Taxonomy (v1) (41).

Workshops

Intervention: The Type 1 Tactics for Exercise group self-management workshop consists of an initial session (3 hours), a booster session (1 hour) 4 weeks later and a peer-led private Facebook group allowing for ongoing group discussion and problem-solving after attendance of the initial session. Intervention content, theory and behaviour change theories have been mapped and are presented in Table 2 and Supplementary Appendix 1. Intervention content relating to current evidence-based strategies to manage blood glucose for PA is based on the consensus statement by Riddell et al (2). The facilitator drew on Social Cognitive Theory (21) and Dual Process Theory (22) to deliver the program content. The intervention workshops were run face-to-face by a facilitator (M.B.) who is an accredited exercise physiologist and credentialled diabetes educator.

Control: The control was a 1-hour "standard care" workshop, followed by another 1-hour booster workshop 4 weeks later. These workshops involved didactic dissemination of standard PA guidelines and basic advice on how to reduce hypoglycemia risk via a PowerPoint presentation (delivered by the same facilitator as the intervention). The facilitator aimed to present the information using as few positive faciliator behaviours as possible and group discussion was kept to a minimum. A Facebook group was not offered. The standard care arm aimed to provide a

118
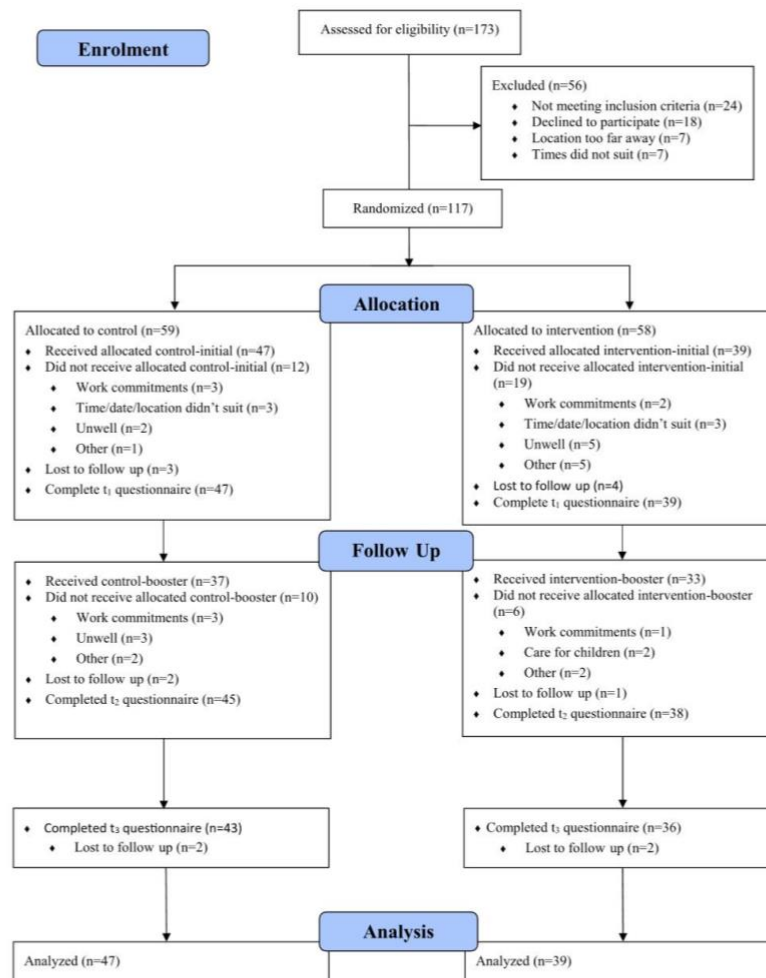
Figure 1. CONSORT flow diagram.

control for the "group effect" that may be observed when gathering like-minded individuals with T1D, whereas the content represented widely available information.

Data collection methods and tools

Primary outcomes:

1. Feasibility and limited aspects of acceptability of the study procedures were measured by examining time and resources involved, recruitment rate, uptake and retention, participant characteristics, completion of questionnaires, nature of missing data and internal reliability of researcher developed tools. Broader aspects of trial and intervention acceptability were assessed using focus group interviews, intervention fidelity assessments and resource and Facebook utility. These will be reported in a future process evaluation study.
2. Change to FoH as a barrier to PA was measured using the Barriers to Physical Activity in Diabetes—Type 1 (BAPAD1) scale (23) (specifically Item 2).

Secondary outcomes:

1. Changes to self-efficacy in: i) physical activity participation and managing blood glucose levels (BGLs) for PA, ii) intentions and attitudes toward PA, iii) self-reported PA, iv) diabetes distress and v) well-being, were measured using:

    I. Self-efficacy measures, developed using Bandura's guide for constructing self-efficacy scales (24).
   II. Attitude and intention measures, developed under the guidance of Fishbein and Ajzen (25).
  III. International Physical Activity Questionnaire—Short Form (26).
   IV. Problem Areas In Diabetes—Short Form (27)
    V. Five-item World Health Organization Well-Being Index (28).

Self-administered questionnaires were completed by both arms of the study immediately before initial intervention/control workshops (t₁), immediately before booster intervention/control

Table 3
Baseline characteristics of study participants

Baseline characteristics	Control	Intervention	All
N	47	39	86
Female, n (%)	24 (51)	24 (62)	48 (56)
Mean age ± SD, years	47±11.15	42±11.68	45±11.68
Ancestry			
English, n (%)	23 (49)	17 (44)	40 (47)
Non-Indigenous Australian, n (%)	21 (45)	14 (36)	35 (41)
Married/partnered, n (%)	32 (68)	28 (72)	60 (70)
Children in their care, n (%)	22 (47)	15 (38)	37 (43)
Highest educational level			
Tertiary, n (%)	24 (51)	22 (58)	46 (54)
Employed, n (%)	35 (74)	33 (85)	68 (79)
Median MET/min/wk (IQR)	2,288 (1,484–4,493)	2,358 (1,409–2989)	2305.50 (1,445–4,166)
Mean ± SD duration of diabetes, years	21.42±15.84	19.17±12.2	20.4±14.27
Diabetes management			
Pump, n (%)	18 (38)	13 (33)	31 (36)
Multiple daily injections, n (%)	26 (55)	23 (59)	49 (57)
Continuous glucose monitoring, n (%)	6 (13)	9 (23)	15 (17)
Flash glucose monitoring, n (%)	13 (28)	12 (31)	25 (29)
Blood glucose monitoring, n (%)	29 (62)	28 (72)	57 (66)
Sought diabetes information from (in last 6 months)			
Diabetes educator, n (%)	22 (47)	19 (49)	41 (48)
Endocrinologist/physician, n (%)	27 (57)	21 (54)	48 (56)
General practitioner, n (%)	24 (51)	19 (49)	43 (50)
Dietitian, n (%)	10 (21)	10 (26)	20 (23)
Exercise physiologist, n (%)	0 (0)	0 (0)	0 (0)
Program/workshop/group session, n (%)	8 (17)	4 (10)	12 (14)
Websites, blogs, social media groups, n (%)	15 (32)	11 (28)	26 (30)
None, n (%)	8 (17)	3 (8)	11 (13)

IQR, interquartile range; *MET/min/wk*, metabolic equivalent minutes per week; *SD*, standard deviation.

workshops (t_2) and 8 weeks after booster workshops (t_3) (Table 1). The full questionnaire was loaded into Qualtrics software (Supplementary Appendix 2) and administered via tablet devices at t_1 and t_2, and home devices at t_3.

Statistical methods

Feasibility outcomes are reported descriptively and narratively. The response rate for e-mail recruitment was calculated by dividing the number of participants assessed for eligibility by the number of successful e-mails sent and opened. It was not feasible to calculate the response rate of other methods of recruitment (social media, flyers and health professional referrals). Recruitment rate was determined by the total number randomized divided by the total months of recruiting.

Given our sample was not powered to detect statistically significant differences between groups, p values are not reported (16). To satisfy objectives examining preliminary efficacy and estimates for future definitive trials, we used Bayesian methods to provide estimates of the distribution of credible values for the effect sizes with regions of practical equivalence (ROPE), group means and standard deviations and their differences. An intention-to-treat analysis was applied. Missing values were treated using 3 methods. In the main text, we report the outcomes from the missing forest analysis ("missForest" package) (29). The LOCF and no imputation methods provided similar estimates and are reported in Supplementary Appendix 3.

To calculate effect sizes for each of the questionnaire scores, we employed Bayesian comparison of the between-group difference scores (i.e. [score$_{t2}$ − score$_{t1}$]$_{TREATMENT}$ vs [score$_{t2}$ − score$_{t1}$]$_{CONTROL}$) using the default options in the BEST package in R (R Core Team, 2020; https://CRAN.R-project.org/package=BEST). The model includes estimates of the mean and standard deviation for each group, and a joint degrees-of-freedom estimate for both groups denoting the shape of the t distribution used to model the

errors (high values denote a normal distribution, low values denote a distribution with greater density in the tails conferring robustness of the model to outliers). Effect sizes are reported as the posterior distribution (100,000 samples were saved after a "burn-in" of 1,000 samples) of standardized mean differences (Cohen's *d*), with corresponding 95% highest density intervals (HDIs). The priors were broad, as described by Kruschke (30). We considered an effect size of less than ±0.2 as practically equivalent to zero, so the ROPE was set at ±0.2 (31). Internal reliability of attitudes, subjective norm, self-efficacy in PA participation and intention scales were calculated using Cronbach's alpha based on t_1 responses with bootstrapped 95% confidence intervals (6,000 samples).

Results

Uptake, retention and attrition

We recruited for a period of 28 weeks, at which time no further expressions of interest were recorded. The initial response, using existing media platforms and print, consisted of 39 expressions of interest over 9 weeks. The largest and most rapid response occurred after targeted mass e-mails. A total of 4,866 e-mails were successfully delivered to T1D National Diabetes Services Scheme registrants via the Diabetes Western Australia database. Of these, 2,024 were opened, and 263 clicked on the information contained in the e-mail. A response rate (e-mail) of 2.8% (6.6% using number of opened e-mails) was achieved with an overall recruitment rate of 12 participants per month over 7 months. Of the 173 participants assessed for eligibility, 149 (86%) were eligible and 117 (79%) consented to randomization. The CONSORT diagram presents participant flow throughout the study (Figure 1). Baseline participant characteristics are shown in Table 3.

A total of 10 intervention and 8 control workshops were delivered with a median of 4 (interquartile range, 3.25 to 4) and 5 (interquartile range, 3.75 to 8.25) participants, respectively, in each

Table 4
Mean difference and standardised effect size

A) t_1 versus t_2

Variable	Mean diff		Effect Size, d	95% HDI	ROPE 0.2	Effect Size (95% HDI)
	Intervention	Control				
BAPAD1 score*	-0.31	-0.11	-0.34	-0.88, 0.19	28.64	
BAPAD1—FoH score*	-0.42	-0.12	-0.33	-1.1, 0.42	30.49	
Self-efficacy (BGLs)—before	4.78	0.2	0.22	-0.27, 0.69	42.33	
Self-efficacy (BGLs)—during	5.97	-0.44	0.2	-0.25, 0.65	46.85	
Self-efficacy (BGLs)—after	13.59	-0.32	0.46	0.01, 0.9	12.76	
Self-efficacy (BGLs) <10m—before[†]	2.58	0.4	0.12	-0.33, 0.57	55.49	
Self-efficacy (BGLs) <10m—during[†]	3.61	1.43	0.11	-0.33, 0.57	56.07	
Self-efficacy (BGLs) <10m—after[†]	11.67	5.34	0.31	-0.14, 0.75	29.88	
Self-efficacy (participation in PA)	-0.18	-0.08	-0.13	-0.59, 0.3	54.16	
Attitudes	0.04	-0.1	0.23	-0.23, 0.71	40.67	
Intentions	-0.26	0.03	-0.35	-0.81, 0.12	25.12	
PA ($\log_{10}$ MET/min/wk)	-0.07	-0.09	0.06	-0.43, 0.53	57.24	
PAID—5 score*	-0.3	-0.12	-0.07	-0.52, 0.38	59.4	
WHO—5 score	4.5	-0.04	0.32	-0.13, 0.76	28.8	

(x-axis: -1, -0.5, 0, 0.5, 1)

B) t_2 versus t_3

Variable	Mean diff		Effect Size, d	95% HDI	ROPE 0.2	Effect Size (95% HDI)
	Intervention	Control				
BAPAD1 score*	-0.09	0.1	-0.36	-0.89, 0.18	25.54	
BAPAD1—FoH score*	0.03	0.49	-0.31	-0.77, 0.14	30.63	
Self-efficacy (BGLs)—before	3.04	0.36	0.18	-0.32, 0.68	46.16	
Self-efficacy (BGLs)—during	2.07	5.33	-0.16	-0.68, 0.34	48.31	
Self-efficacy (BGLs)—after	2.13	9.43	-0.23	-0.68, 0.2	41.42	
Self-efficacy (BGLs) <10m—before[†]	3.06	-0.06	0.21	-0.28, 0.69	43.25	
Self-efficacy (BGLs) <10m—during[†]	0.91	-2.62	0.19	-0.27, 0.64	47.31	
Self-efficacy (BGLs) <10m—after[†]	-1.88	-3.94	0.1	-0.35, 0.53	58.46	
Self-efficacy (participation in PA)	-0.03	-0.2	0.37	-0.15, 0.91	24.87	
Attitudes	-0.15	-0.25	0.15	-0.33, 0.62	50.22	
Intentions	-0.06	-0.22	0.26	-0.25, 0.76	37.25	
PA (log10 MET/min/wk)	0.03	-0.2	0.17	-0.33, 0.65	48.55	
PAID—5 score*	-0.78	-0.09	-0.38	-0.89, 0.12	22.89	
WHO—5 score	-0.26	-1.07	0.05	-0.41, 0.51	59.22	

(x-axis: -1, -0.5, 0, 0.5, 1)

C) t_1 versus t_3

Variable	Mean difference		Effect Size, d	95% HDI	ROPE 0.2	Effect Size (95% HDI)
	Intervention	Control				
BAPAD1 score*	-0.29	-0.06	-0.38	-0.92, 0.17	24.7	
BAPAD1—FoH score*	-0.41	-0.1	-0.17	-0.63, 0.3	48.63	
Self-efficacy (BGLs)—before	8.38	-0.23	0.43	-0.06, 0.91	17.27	
Self-efficacy (BGLs)—during	11.38	6.71	0.15	-0.31, 0.61	52.12	
Self-efficacy (BGLs)—after	16.39	8.6	0.29	-0.17, 0.75	33.48	
Self-efficacy (BGLs) <10m—before[†]	5.41	-0.79	0.32	-0.15, 0.77	29.43	
Self-efficacy (BGLs) <10m—during[†]	5.44	-1.44	0.31	-0.14, 0.76	30.38	
Self-efficacy (BGLs) <10m—after[†]	10.46	1.53	0.45	0, 0.91	13.13	
Self-efficacy (participation in PA)	-0.26	-0.23	-0.04	-0.57, 0.46	55.09	
Attitudes	-0.11	-0.3	0.28	-0.23, 0.78	33.36	
Intentions	-0.28	-0.18	-0.11	-0.59, 0.37	53.71	
PA (log10 MET/min/wk)	-0.03	-0.11	0.31	-0.21, 0.83	30.77	
PAID—5 score*	-0.89	-0.16	-0.29	-0.77, 0.15	33.14	
WHO—5 score	4.32	-1.2	0.36	-0.12, 0.8	24.07	

(x-axis: -1, -0.5, 0, 0.5, 1)

BAPAD1, Barriers to Physical Activity in Diabetes—type 1 scale; *BGL*, blood glucose level (<10 m = values <10 treated as missing); *FoH*, fear of hypoglycemia; *HDI*, highest density interval; *MET/min/wk*, metabolic equivalent minutes per week; *PA*, physical activity; *PAID-5*, Problem Areas In Diabetes 5-item scale (diabetes distress); *ROPE*, region of practical equivalence; *WHO-5*, 5-item World Health Organization Well-Being Index (28).
Note: Green favours the intervention and red favours the control.

* Negative values are desirable.

[†] Questionnaire items measuring self-efficacy in managing BGL before, during and after PA were abnormally low, possibly due to user-related error in operating the sliding scale on the tablet. Therefore, we also present analyses with values <10 treated as missing.

group at t_1. All but 1 (intervention) workshop were delivered within predetermined group size limits. The greatest dropout rate (26%) was seen between t_0 and t_1 (33% intervention, 20% control). Retention from t_1 to t_2 was 81% (85% intervention, 79% control). Questionnaire completion from t_1 to t_2 was 97% (97% intervention, 96% control) and from t_2 to t_3 was 95% (95% intervention, 96% control). The characteristics of participants who withdrew after t_1 presented in Supplementary Appendix 4.

There were no reported adverse events during the course of the trial. There was no change in self-reported episodes of severe hypoglycemia, nor hypoglycemia.

Barriers to physical activity and FoH

A small-to-moderate effect in favour of the intervention was observed in BAPAD1 scores across all time points. To examine the intervention's potential effect on FoH as a barrier, we highlight Item 2 of the BAPAD1, which demonstrates high discriminating power ("the risk of hypoglycemia," item-total correlation = 0.67) (23). A small-to-moderate effect was detected in favour of the intervention between t_1 and t_2, but from t_1 to t_3 the effect had fallen (Table 4). A subanalysis of less active participants (<1,000 metabolic equivalents [METs]/min/week; control, n=8; intervention, n=5) suggested large effects in favour of the intervention in BAPAD1 score and Item 2 (Supplementary Appendix 3).

Secondary outcomes

Outcomes, including attitudes and intentions toward PA, self-efficacy in managing BGL, self-efficacy in PA participation, self-reported PA, diabetes distress and well-being, are reported in Table 4. Internal reliability (alpha) for attitudes, intention and self-efficacy in PA participation scales was 0.80 (0.73 to 0.86), 0.89 (0.80 to 0.94) and 0.79 (0.67 to 0.86), respectively. The subjective norm scale was not internally reliable, alpha = 0.61 (0.47 to 0.71), and was excluded from the analysis. Notable small-to-moderate effects in favour of the intervention seen from t_1 to t_2 were found in self-efficacy managing BGL after PA and in well-being. Diabetes distress scores had a small-to-moderate effect size toward the intervention, between t_2 and t_3. Effect sizes between t_1 and t_3 were noteworthy across all self-efficacy scales (managing BGL before, during and after PA, <10 treated as missing). A small-to-moderate effect toward the intervention was also detected for well-being during this period. There were no reported adverse events during the course of the trial. There was no change in self-reported episodes of severe hypoglycemia or hypoglycemia.

Discussion

Our single-blinded, pilot RCT design was acceptable to participants and feasible to administer with a modest research budget. Men and women, with a mean age of 45 years, who were already active and living with T1D for >20 years, were most willing to participate. Preliminary findings indicated small-to-moderate effect sizes in favour of the intervention after 12 weeks, in relation to overall barriers to PA, self-efficacy (BGL management for PA), diabetes distress and well-being.

The most successful recruitment method was mass e-mail distribution, which facilitated a response rate of 2.8% (6.6% from opened e-mails), marginally lower than rates reported in other RCTs of group interventions using mail-out recruitment methods (32). Our recruitment rate of 12 participants per month was lower than that of other group RCTs with a similar recruitment period (7 months). Nevertheless, it was higher than the recruitment rate in the REPOSE trial (recruitment rate of 2.4 over 16.7 months), a trial of self-management group education for people with T1D (32,33).

Although our target sample size was achieved, subsequent attrition rates (from t_0 to t_1) were high (26%) but similar to other behavioural programs for diabetes (13,34). The final sample of 86 was adequate to provide statistical parameters for future definitive trials (18). We did anticipate a high initial dropout rate because attendance was governed by participants' availability for prescheduled intervention/control workshops. Many participants, upon being allocated, were subsequently unable to attend scheduled workshops despite multiple time, date and location options. Although the intervention arm experienced greater initial attrition than the control arm, retention improved (from 67% to 85%) in the intervention arm from t_1 to t_2. We postulate this initial dropout was due to the greater time commitment required of intervention participants; once able to commit, participants in this arm were more likely to return for the booster. Being unwell was among the most frequently cited reasons for withdrawal between t_0 and t_1. Satisfactory recruitment rates, retention rates and willingness to be randomized indicate the study procedures were acceptable to research participants.

Although group sizes were within predetermined limits, they were small with a median of 4 (3.25 to 4) participants in each intervention group. Generally, 5 to 7 participants is considered optimal for behaviour change interventions, particularly when applying Social Cognitive Theory (19,20). Small group sizes may have compromised participants' opportunity to experience social learning and modelling, but may have improved relatedness between members and decreased the likelihood of "social loafing" (19). Future trials should consider a longer intervention delivery phase (lower "delivery rate") to provide greater opportunity to fill groups before they commence.

Experiencing fewer barriers to PA is correlated with greater PA participation in this population (35), yet changes to barriers to PA have not been reported in RCTs to date. We observed a small-to-moderate effect size in change to overall BAPAD1 score in favour of the intervention between t_1 and t_3. Although a "clinically significant" change has not been defined for this tool, this improvement indicates the intervention contains crucial components required to facilitate PA behaviour change and is worth investigating in a larger trial. Although we detected some effect of the intervention on FoH as a barrier between t_1 and t_2, we did not see the same magnitude from t_1 to t_3. More opportunities for skills mastery, role modelling, vicarious learning and exploring psychological affect are required to further impact FoH as a barrier (21). One way to do this could be by increasing the number and duration of booster sessions and including peer-led postintervention support groups.

We measured self-reported PA and used measures of self-efficacy, intentions and attitudes toward PA to predict the likelihood of future PA behaviour change (21,25). The intervention had a small-to-moderate effect on self-efficacy in managing BGLs before, during and after PA at beyond 12 weeks and, although predetermined benchmarks are not available, we believe this improvement was meaningful (Table 4). There was little to no meaningful effect in self-efficacy for PA participation, attitudes, intentions or self-reported PA across the 12-week follow-up period. Previous trials have measured changes to self-efficacy for PA participation and self-care, but not specifically for managing BGLs for PA (10,12,36). Improving self-efficacy in managing BGLs for PA is an important first step toward a more active T1D population (37). Future trials should focus on improving confidence in PA participation and attitudes and intentions toward PA in order to enhance actual PA participation.

Although improvements to well-being did not reach benchmarks for clinical significance and benchmarks for meaningful change in Problem Areas in Diabetes Scale-5 scores do not exist, the intervention has shown promise in its positive effects on these outcomes (28). A small number of T1D PA behaviour studies have used well-being and diabetes distress as outcome measures, but

none showed significant or noteworthy effects (12,13,38). Although many confounding factors to well-being and diabetes distress exist, our pilot study has indicated that participants' well-being and mental health were not compromised and may have benefited from participating in group self-management PA education.

Limitations

The control group was designed to mimic "standard care" and account for group effects, although we suspect what was delivered may have been over and above what the average person with T1D is generally exposed to. It is possible the relative effects of the intervention were diminished by having an active rather than passive control.

Although our recruitment material attempted to target a less active cohort, we did not exclude participants based on activity level. Our sample was very active at baseline compared with the wider T1D population and may not be representative of this population (5–8). Higher baseline activity rates may have also limited the scope of improvement in PA. Furthermore, a subanalysis indicated those reporting <1,000 METs/min/week at baseline may have had a more pronounced reduction in overall barriers and FoH as a barrier. Although this analysis should be interpreted with caution owing to the small sample, it suggests those who are less active may have more to gain from the intervention. Future recruitment plans and exclusion criteria should be adjusted to target a less active, more representative cohort, similar to those used by Brazeau et al (10). Adopting this strategy may reduce recruitment rates and require a longer recruitment period and may necessitate further consultation with inactive T1D representatives to inform future recruitment strategies. As PA participation was not a primary outcome of this pilot RCT, we did not use objective device-driven measures of PA. Self-reported PA questionnaires are subject to reporting bias and may not have accurately reflected activity levels in our sample (39). Future trials should consider the use of device-measured PA outcomes, particularly if PA participation is a primary outcome. Patterns of missing or abnormally low data were found among responses to the self-efficacy scale (managing BGLs for PA). We postulate this was due to user-related error in operating the sliding scale on the tablets provided. We suggest this item display be changed and piloted before being used in future trials.

Our sample did not allow examination of the confounding effects of the insulin delivery method and/or use of continuous/flash glucose monitoring on primary and secondary outcomes. Future definitive trials should consider these potential confounders to identify whether there is a need to provide separate education based on participants' choice of diabetes technology.

A limitation of our study is that the first author (a PhD candidate) recruited, screened and randomized participants, facilitated all control and intervention sessions and collected the data. Potential bias was abated by close supervision from experienced members of the research team throughout the study. Furthermore, there was nothing in the reported findings to indicate potential bias.

Implications and conclusions

Preliminary quantitative evidence suggests theory-driven self-management group education on the complex topic of T1D management for PA is a feasible and acceptable mode of education for adults living with T1D. We have demonstrated small-to-moderate effect sizes in favour of the intervention on a number of diabetes outcomes which are considered important for future PA behaviour change. We suspect that once individuals have addressed "diabetes-specific" barriers to PA and are confident in managing their BGLs for PA, they will be better placed to receive

aspects of behaviour change interventions. Diabetes health professionals should strive to offer self-management group education on this topic for those who are insufficiently active in an effort to decrease diabetes-specific barriers to PA.

Participant uptake, retention and attrition; successful data collection; and timely study completion indicate that a single-blinded RCT is acceptable to participants and feasible to deliver. Adjustments to recruitment and exclusion criteria may be required to include a less physically active cohort. Future trials may also consider revised control delivery to better reflect "standard care" in Australia. A future definitive trial is justified to determine the utility of the intervention in improving PA participation.

Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Diabetes* at www.canadianjournalofdiabetes.com.

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Appendix B Publication Appendix

The following appendix includes supplements of the publication presented above. Online versions are also available at

www.canadianjournalofdiabetes.com.

Supplementary Appendix 1

Type 1 TACTICS for Exercise© Program Summary

Section	Content	Theories in action	Behaviour Change Techniques
Section 1: Introduction, housekeeping and program overview	• Questions • Introduce participant resources • Current PA recommendations • Barriers to PA • Program overview	• <u>Skills Mastery – self-reflection</u> to elicit some current knowledge, beliefs and barriers surrounding PA.	1.2 Problem solving 5.1 Information about health consequences 6.2 Social comparison
Section 2: Carbohydrate metabolism	• Pathophysiology of T1D and PA •	• <u>Dual Processing</u> to allow participants the opportunity to discover and learn about their diabetes and how PA impacts on BGL. • Open discovery questions allow participants to reflect and continue to discover how things work, what goes wrong and what could help. • <u>Skills Mastery – self-reflection</u> to encourage participants to share experience of participating in PA and their beliefs surrounding how much PA is required	5.1 Information about health consequences 6.2 Social comparison 16.3 Vicarious consequences

		• <u>Physical and psychological affect</u> to explore feelings and experiences of physical signs of hypo and hyperglycaemia. • <u>Verbal Persuasion </u>to elicit knowledge and beliefs surrounding why we experience excursions in BGL with PA.	
Section 3: Preparing for exercise	• Planning for PA • Contraindications to PA •	• <u>Verbal Persuasion </u>to elicit knowledge and beliefs surrounding what factors may influence BGL for PA • <u>Skills Mastery – self-reflection</u> to share experience of participating in PA and reflection on what they have considered in preparing for PA in the past.	11.3 Conserving mental resources 16.3 Vicarious consequences
Section 4: Blood glucose levels	• Monitoring BGL • Targets • Introduce the 'timeline activity'	• <u>Verbal Persuasion </u>to enable participants to share their experience and knowledge surrounding monitoring • <u>Skills Mastery – self-reflection</u> to share their experience of monitoring and reflection on what has worked for them in the past	6.2 Social comparison 8.6 Generalisation of target behaviour 11.3 Conserving mental resources 15.3 Focus on past success 16.3 Vicarious consequences
Section 5: Carbohydrate intake	• Carbohydrate's role in general diet and for exercise • Recommended carbohydrate intake • Build timeline activity to include carbs	• <u>Skills Mastery</u> to encourage self-reflection throughout this section to encourage participants to talk about their current knowledge and experience when it comes to using carbohydrate/insulin as strategies to manage BGL. • <u>Role Modelling </u>can be seen in this section with participants group solving how they might be able to identify carbohydrate and how to use	4.1 Instruction on how to perform the behaviour 4.2 Information about antecedents 6.1 Demonstration of the behaviour 6.2 Social comparison 8.1 Behaviour practice/rehearsal 8.7 Graded tasks 9.3 Comparative imaging of future outcomes

		carbohydrate/insulin in managing BGL. • <u>Role Modelling</u> may also be used to encourage the group to share any problems they had with these strategies in the past and what they learnt from that. Encourage the group to discuss possible solutions for these problems. • <u>Skills Mastery</u> to encourage successful trial and pro-active self in timeline activities looking at using carbohydrate and insulin adjustment.	11.3 Conserving mental resources 15.3 Focus on past success 16.3 Vicarious consequences
Section 6: Insulin	• Insulin pharmacokinetics • Use timeline activity to explore the effect of bolus insulin • Basal insulin	• As above	4.1 Instruction on how to perform the behaviour 4.2 Information about antecedents 6.1 Demonstration of the behaviour 6.2 Social comparison 8.1 Behaviour practice/rehearsal 8.7 Graded tasks 9.3 Comparative imaging of future outcomes 11.3 Conserving mental resources 15.3 Focus on past success 16.3 Vicarious consequences
Summary	• Exercise diary • Facebook support group and/or email contact • Review key messages • Reflection	• <u>Verbal persuasion</u> to elicit positive outcomes they might expect from using new strategies and PA as part of their diabetes self-management • <u>Skills mastery -</u> participants to think about which strategy they can apply from the session that would enhance their own diabetes self-management	2.3 Self-monitoring of behaviour 3.1 Social support (unspecified) 3.3 Social support (emotional) 4.2 Information about antecedents 5.4 Monitoring of emotional consequences

Goal setting	• My Action Plan worksheet	• <u>Verbal persuasion </u>to support participants to set goals at the end of the session and to plan for obstacles • <u>Role modelling</u> to discuss and share any problems they think they'll have with goal setting and explores any lack of confidence •	Goal setting (behaviour) Problem solving Goal setting (outcome) Action planning 15.1 Verbal persuasion about capability

• Type 1 TACTICS for Exercise© – Booster Session

Section	• Content	• Theories in action	Behaviour Change Techniques
Section 1: Introduction	• Welcome participants back • Goals • Questions	• <u>Verbal persuasion </u>to encourage all participants to talk about what they have found out • <u>Role modelling – sharing obstacles</u> to give participants opportunities to discuss problems they encountered and to explore lack of confidence	5.4 Monitoring of emotional consequences 6.2 Social comparison 15.1 Verbal persuasion about capability
Section 2: Scenarios	• Discuss PA scenarios • Work through scenarios	• <u>Skills mastery</u> encourages participants to share experience of participating in physical activity and their beliefs surrounding how and why some strategies did or did not work. Successful trial to use learned strategies in timeline activity. • <u>Verbal persuasion</u> to encourage all participants to talk about what they now know in relation to managing BGLs for PA • <u>Physical and Emotional Management</u> to encourage participants to express any emotions, beliefs or experiences	3.1 Social support (unspecified) 3.3 Social support (emotional) 4.2 Information about antecedents 5.4 Monitoring of emotional consequences 6.1 Demonstration of the behaviour 6.2 Social comparison 8.1 Behaviour practice/rehearsal 11.3 Conserving mental resources 15.3 Focus on past success 16.3 Vicarious consequences

		they have associated with hypoglycaemia (If this comes up)	
Section 3: Conclusions	• Revisit barriers to PA from four weeks ago • Revisit burning questions from four weeks ago • Revisit goal setting	• <u>Role modelling</u> to encourage participants to share how they may overcome barriers • <u>Verbal persuasion</u> - barriers discussed are used to elicit strategies for planning for obstacles • <u>Skills mastery</u> to encourage participants to reflect on their prior experience of action planning	1.1 Goal setting (outcome) 1.2 Problem solving 1.3 Goal setting (behaviour) 1.4 Action planning 2.3 Self-monitoring of behaviour 3.1 Social support (unspecified) 3.3 Social support (emotional) 4.2 Information about antecedents 8.7 Graded tasks 15.1 Verbal persuasion about capability

Supplementary Appendix 2

Appendix S2 – Questionnaire

Pre-evaluation – Type 1 diabetes and Physical Activity

Thank you for agreeing to take part in this study. Before we begin, we would appreciate if you could take 15 minutes to complete this questionnaire. Your responses will help us to continue delivering interesting and useful sessions for people with diabetes.

By completing and submitting this questionnaire, you are giving your consent to participate in this part of the study. Once the questionnaire is submitted, your data cannot be withdrawn because your responses are de-identified.

Please fill in your unique code:

Your post code:

☐ ☐ ☐ ☐

The last 3 numbers of your mobile number:

☐ ☐ ☐

Today's date_____

---

1. Your age (in years): _____

2. Gender:

   ☐ Male   ☐ Female   ☐ Other

3. Are you attending today's session with anyone (partner, support person, friend)?

   ☐ Yes   ☐ No

4. What is your ancestry? (provide up to 2 ancestries only)

   ☐ English   ☐ Irish   ☐ Italian

   ☐ German   ☐ Chinese   ☐ Scottish

   ☐ Australian   ☐ Aboriginal or Torres Strait Islander   ☐ Other _____

5. Do you have a spouse or a partner and, if yes, do you share the same household?

[ ] Yes, and we share the same household   [ ] Yes, but we do not share the same household   [ ] No, I do not have a spouse/partner

6. Do you have any children or others in your care?

[ ] No   [ ] Yes   How many? [ ]

7. Are you currently studying at school or any other educational institution?

[ ] No   [ ] Yes, full-time student   [ ] Yes, part-time student

8. During the last week, did you have a job of any kind? (A 'job means any type of work including casual, temporary, part-time or full-time, if it was for one hour or more)

[ ] Yes, worked for payment or profit   [ ] Yes, but absent on holidays, on paid leave, on strike or temporarily stood down   [ ] Yes, unpaid work in a fan business

[ ] Yes, other unpaid work   [ ] No, did not have a job

9. What is the highest education level you have completed?

[ ] No formal schooling   [ ] Primary school   [ ] Some secondary school

[ ] Year 12 or equivalent   [ ] Trade qualification or apprenticeship   [ ] Certificate or diploma (T/

[ ] Tertiary

10. How long have you been diagnosed with type 1 diabetes?
_____ years and _____ months.

11. Which device(s) do you currently use *regularly* to manage your diabetes? (Tick those that apply)

[ ] Multiple daily injections   [ ] Pump

[ ] Continuous Glucose Monitoring (CGM)   [ ] Flash Glucose Monitoring (Libre)

☐ Finger prick monitoring   ☐ I do not monitor regularly

12. Do you have any known **complications** of diabetes? If so, please list below.

```
┌─────────────────────────────────────────────────────────────┐
│                                                             │
│                                                             │
│                                                             │
└─────────────────────────────────────────────────────────────┘
```

13. How many events of hypoglycaemia (blood glucose levels less than 4 mmol/L) have you experienced in the last **14 days**?_____.

14. How many of these events occurred **during** or up to **12 hours** after physical activity (physical activity may be activities you do for work, house or yard work, walking from place to place, recreation activities, exercise or sport)? _____.

15. Have you experienced any episodes of **severe** hypoglycaemia (requiring the assistance of another person) within the last **12 months**?

☐ Yes   ☐ No

16. During the **last 6 months**, have you attended or sought information from any of the following for your **diabetes**? Please tick relevant box(s).

☐ Diabetes educator   ☐ Endocrinologist/ general physician   ☐ Dietitian

☐ Exercise physiologist   ☐ GP   ☐ None

☐ Program / Workshop / Group session.
What was the name of the program?_____
Where did you attend?_____

☐ Websites, blogs, social media groups (excluding the study Facebook group)

The next 6 questions refer to activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport. Think only about those physical activities that you did for at least 10 minutes at a time.

17. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **days per week**

☐ No vigorous physical activities ➡ *Skip to question 19*

18. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

19. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week**

☐ No moderate physical activities ➞ *Skip to question 21*

20. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

21. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking ➞ *Skip to question 23*

22. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

23. Please indicate the likelihood that each of these items would keep you from meeting your physical activity goals over the next 6 months?

	Extremely Unlikely	Very Unlikely	Somewhat Unlikely	Neutral	Somewhat Likely	Very Likely	Extremely Likely
The loss of control over your diabetes	1	2	3	4	5	6	7
The risk of hypoglycaemia	1	2	3	4	5	6	7
The fear of being tired	1	2	3	4	5	6	7
The fear of hurting yourself	1	2	3	4	5	6	7
The fear of suffering a heart attack	1	2	3	4	5	6	7
A low fitness level	1	2	3	4	5	6	7
The fact that you have diabetes	1	2	3	4	5	6	7
The risk of hyperglycaemia	1	2	3	4	5	6	7
Your actual physical health status excluding your diabetes	1	2	3	4	5	6	7
Weather conditions	1	2	3	4	5	6	7
The location of a gym	1	2	3	4	5	6	7

Please respond to the following by circling the number that best reflects how you feel about the following statements.

24. My participation in physical activity for at least 30 minutes, 5 days per week for the next month would be:

Bad   1   2   3   4   5   6   7   **Good**

25. My participation in physical activity for at least 30 minutes, 5 days per week for the next month would be:

Unpleasant   1   2   3   4   5   6   7   **Pleasant**

26. My participation in physical activity for at least 30 minutes, 5 days per week for the next month would be:

Not worthwhile   1   2   3   4   5   6   7   **Worthwhile**

27. My participation in physical activity for at least 30 minutes, 5 days per week for the next month would be:

| Harmful | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Beneficial |

28. Most people who are important to me approve of my participation in physical activity for at least 30 minutes, 5 days per week for the next month.

| Disagree | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Agree |

29. Most people like me, who have type 1 diabetes participate in physical activity for at least 30 minutes, 5 days per week.

| Unlikely | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Likely |

30. Most people who are important to me would pressure me to participate in physical activity for at least 30 minutes, 5 days per week for the next month.

| Disagree | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Agree |

31. Most people who are important to me encourage me to participate in physical activity for at least 30 minutes, 5 days per week for the next month.

| Disagree | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Agree |

32. I am confident I can participate in physical activity for at least 30 minutes, 5 days per week for the next month.

| Not confident | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Confident |

33. My participation in physical activity for at least 30 minutes, 5 days per week for the next month is up to me.

| Disagree | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Agree |

34. I am in complete control of participating in physical activity for at least 30 minutes, 5 days per week for the next month.

| Disagree | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Agree |

35. If I wanted to, I could participate in physical activity for at least 30 minutes, 5 days per week for the next month.

| Disagree | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Agree |

36. I intend to participate in physical activity for at least 30 minutes, 5 days per week for the next month.

| Unlikely | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Likely |

37. I am determined to participate in physical activity for at least 30 minutes, 5 days per week for the next month.

| **Disagree** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | **Agree** |

38. I want to participate in physical activity for at least 30 minutes, 5 days per week for the next month.

| **Disagree** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | **Agree** |

39. In the past 3 months I have participated in at least 30 minutes of physical activity, 5 days per week.

| **False** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | **True** |

For questions 40 – 42, please rate your degree of confidence by recording a number from 0 to 100 using the scale given below:

| 0 | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 | 100 |

Cannot do at all   Moderately can do   Highly certain can do

40. Confidence to keep my blood glucose levels within my target range *immediately before* physical activity _____.

41. Confidence to keep my blood glucose levels within my target range *during* physical activity _____.

42. Confidence to keep my blood glucose levels within my target range *up to 12 hours after* physical activity _____.

43. **Which of the following diabetes issues are currently a problem for you? Circle the number that gives the best answer for you. Please provide an answer for each question.**

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
Feeling scared when you think about living with diabetes					
Feeling depressed when you think about living with diabetes					
Worrying about the future and the possibility of serious complications					
Feeling that diabetes is taking up too much of your mental and physical energy every day					
Coping with complications of diabetes					

44. Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better well-being.

	All of the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	None of the time
I have felt cheerful and in good spirits						
I have felt calm and relaxed						
I have felt active and vigorous						
I woke up feeling fresh and rested						
My daily life has been filled with things that interest me						

End of questionnaire – Thank you!

Supplementary Appendix 3

Supplementary appendix 3 exists as a Microsoft Excel® spreadsheet with large data sets spanning multiple tabs and is too large to include in the thesis document. To access this file, please refer to the online article https://doi.org/10.1016/j.jcjd.2021.01.001.

Supplementary Appendix 4

Characteristics of Participants Who Withdrew After t_1

Characteristics	Control	Intervention	All
n (%)	11 (23)	6 (15)	17 (20)
Female, *n* (%)	7 (64)	4 (67)	11 (65)
Mean age ± SD (years)	45 ±11.01	41 ±6.89	44 ±9.77
Ancestry			
English, *n* (%)	5 (45)	2 (33)	7 (41)
Non-Indigenous Australian, *n* (%)	4 (36)	2 (33)	6 (35)
Married/partnered, *n* (%)	7 (64)	4 (67)	11 (65)
Children in their care, *n* (%)	6 (55)	4 (67)	10 (59)
Highest educational level			
Tertiary, *n* (%)	6 (55)	2 (40)	8 (50)
Employed, *n* (%)	9 (82)	5 (83)	14 (82)
Median MET.min.wk (*IQR*)	2079 (1770, 3853)	2999 (2400, 5586)	2699 (1879, 4637)
Mean duration of diabetes ± SD (years)	20 ±13.98	21 ±8.92	21 ±12.13
Diabetes management			
Pump, *n* (%)	6 (55)	2 (33)	8 (47)
Multiple daily injections, *n* (%)	4 (36)	4 (67)	8 (47)
Continuous glucose monitoring, *n* (%)	2 (18)	1 (17)	3 (18)
Flash glucose monitoring, *n* (%)	5 (45)	1 (17)	6 (35)
Blood glucose monitoring, *n* (%)	4 (36)	5 (83)	9 (53)

Note. MET.min.wk – metabolic equivalent minutes per week

4.2 Process Evaluation of Study Procedures, the Intervention, and the Control

Brennan, M. C., Brown, J. A., Leslie, G. D., & Ntoumanis, N. (2021). Acceptability of self-management group education to reduce fear of hypoglycemia as a barrier to physical activity in adults with type 1 diabetes: A mixed methods approach. *Canadian Journal of Diabetes*. *Advance online publication.* https://doi.org/10.1016/j.jcjd.2021.04.008

Original Research

Acceptability of Self-Management Group Education to Reduce Fear of Hypoglycemia as a Barrier to Physical Activity in Adults With Type 1 Diabetes: A Mixed Methods Approach

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Key Messages

- Quantitative evaluation of Type 1 TACTICS for Exercise designed to reduce T1D-specific barriers demonstrated feasibility, preliminary efficacy and acceptability.
- We provide further evidence that Type 1 TACTICS for Exercise is acceptable to adults living with T1D and is a preferred mode of education for this complex issue.
- Basic information, including general PA guidelines and hypoglycemia risk/management, is not standard knowledge for all adults living with T1D.

ABSTRACT

Objectives: Mixed methods were used to evaluate a group self-management education intervention to address type 1 diabetes (T1D)-specific barriers to physical activity (PA). We evaluated the acceptability of study resources and procedures.
Methods: Consenting participants from a quantitative evaluation (n=70) were invited to participate in 1 of 5 focus groups. Interviews explored the acceptability of procedures across the randomized controlled trial schedule, acceptability of the intervention/control workshops and resources and the perceived effectiveness of the intervention/control on participant outcomes. The use and helpfulness of intervention take-home resources, Facebook data and fidelity coding were also examined to inform other aspects of intervention acceptability.
Results: Twenty-one focus group participants from control or intervention arms participated in 1 of the 5 focus groups. Participants were 46±10 years of age; about half were female and had been living with T1D for 23±16 years. Study procedures were widely accepted; however, randomization and some aspects of the questionnaire were of concern to a small number of participants. Group education was acceptable and preferred, but participants expressed ambivalence toward the private Facebook group. Control participants indicated that basic information on PA guidelines and hypoglycemia risk are not currently being provided in standard care. Fidelity assessment confirmed the intervention was delivered consistently and was facilitated using behaviours and communication skills based on Social Cognitive Theory.
Conclusions: Future definitive evaluation of this promising intervention should utilize a blinded randomized controlled trial study design. Alterations to the control workshop are required to better reflect

standard care in Australia. Our qualitative findings suggest that group education can be an acceptable and preferred method of education in T1D management for PA.

Mots clés:
adultes
diabète sucré de type 1
exercice
crainte de l'hypoglycémie
éducation à la santé
prise en charge autonome

R É S U M É

Objectifs : Nous avons utilisé des méthodes mixtes pour évaluer un groupe d'intervention en éducation à la prise en charge autonome afin de nous pencher sur les obstacles à l'activité physique (AP) chez les diabétiques de type 1 (DT1). Nous avons évalué l'acceptabilité des ressources et des procédures de l'étude.

Méthodes : Nous avons invité les participants consentants d'une évaluation quantitative (n = 70) à participer à 1 des 5 groupes de discussion. Les entrevues ont permis d'examiner l'acceptabilité des procédures dans le calendrier de l'essai clinique à répartition aléatoire, l'acceptabilité des ateliers intervention/témoin et des ressources, et de l'efficacité perçue des ateliers intervention/témoin sur les résultats des participants. Nous avons également examiné l'utilisation et l'utilité des ressources d'intervention à faire à la maison, des données de Facebook et de la codification de la fidélité pour comprendre d'autres aspects de l'acceptabilité de l'intervention.

Résultats : Vingt et un participants aux groupes de discussion des bras témoin ou intervention ont participé à 1 des 5 groupes de discussion. Les participants avaient 46 ± 10 ans; environ la moitié était des femmes et vivait avec le DT1 depuis 23 ± 16 ans. Les procédures de l'étude étaient très bien acceptées. Toutefois, un petit nombre de participants étaient préoccupés par la répartition aléatoire et certains aspects du questionnaire. Les participants acceptaient et préféraient l'éducation en groupe, mais ils exprimaient une ambivalence concernant le groupe privé Facebook. Les participants témoins ont indiqué que les informations de base sur les lignes directrices en matière d'AP et le risque d'hypoglycémie ne sont actuellement pas données lors des soins courants. L'évaluation de la fidélité a confirmé que l'intervention était régulièrement offerte et qu'elle était facilitée par les comportements et les capacités de communication fondées sur la théorie sociocognitive.

Conclusions : L'évaluation définitive future de cette intervention prometteuse devrait reposer sur l'utilisation d'une conception d'essai à répartition aléatoire à l'insu. Des modifications à la séance témoin sont nécessaires pour mieux refléter les soins usuels de l'Australie. Nos résultats qualitatifs montrent que l'éducation en groupe est une méthode d'éducation à la prise en charge de l'AP chez les DT1 qui est acceptable et privilégiée.

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Introduction

Regular physical activity (PA) improves cardiovascular health, blood glucose (BG) management, insulin-dose requirements and well-being in people living with type 1 diabetes (T1D) (1,2). Although meeting recommended PA guidelines can be difficult for everyone (3–6), people living with T1D may experience even greater challenges, as evidenced by their higher rates of insufficient activity (4,7–9). A recent systematic scoping review addressed barriers to PA in adults living with T1D and showed hypoglycemia and fear of hypoglycemia (FoH) to be the most cited barriers (10). Successful, safe participation in PA requires advanced knowledge, self-management skills and self-efficacy from the person living with T1D. Without careful adjustment of insulin and carbohydrate, dramatic fluctuations in BG occur during and after activity (11). To avoid the unpleasant symptoms of hypoglycemia, people with T1D may not engage in PA. Few interventions aiming to address "diabetes-specific" barriers to PA have been trialled and none have explicitly targeted FoH (10). Of those investigators who did trial interventions (12–17), most recruited small samples and few used robust study designs, and only 2 reported elements of trial or intervention acceptability (15,17).

A theory-driven, group education intervention—Type 1 TACTICS for Exercise—was developed to address "diabetes-specific" barriers to PA in adults, including FoH and lack of knowledge to manage blood glucose levels (BGLs) for PA (18). The intervention consisted of an initial 3-hour self-management education session; a 1-hour booster session 4 weeks later; and a peer-led private Facebook group to facilitate ongoing group discussion, role-modelling and problem-solving. Intervention delivery was guided by Social Cognitive Theory (19) and Dual Process Theory (20), and content was based on current evidence-based strategies to manage BG for PA (11). The control ("standard care") was delivered using a didactic PowerPoint presentation using content that was widely available. Control participants attended an initial 1-hour session, followed by another 1-hour booster session 4 weeks later. A Facebook group was not offered to control participants. Further details of the intervention and control have been reported elsewhere (18). We aimed to evaluate the feasibility, acceptability and preliminary efficacy of Type 1 TACTICS for Exercise using mixed methods (Figure 1). Our first report detailed feasibility, preliminary efficacy and limited aspects of acceptability of study procedures of a pilot randomized controlled trial (RCT) (18). In this study we report broader aspects of the acceptability of study procedures, the intervention and control, including perceived impact on primary and secondary outcomes. Comprehensive assessment of acceptability is an essential component of process evaluation, particularly before proceeding to larger definitive trials (21,22).

Methods

Research design

We used a 2-phase, explanatory sequential mixed methods design, as summarized in Figure 2 (23,24). The initial quantitative phase was a single-blind, pilot RCT of adults with T1D who were
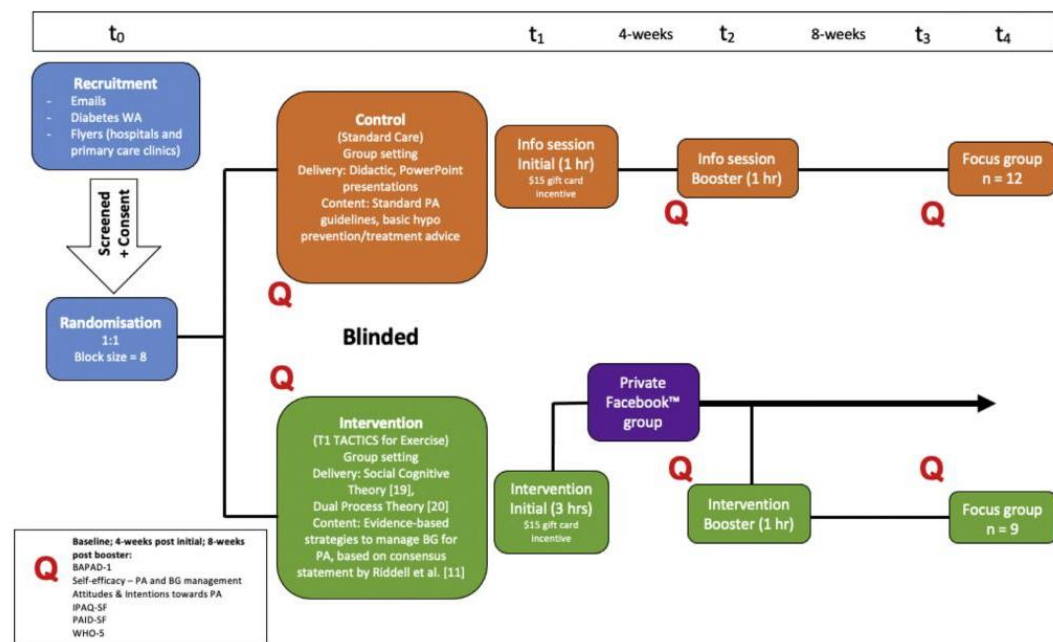
Figure 1. Study schedule. Time periods: t_0, over a 7-month period, allocation within 1 week of enrolment; t_1, within 1 month of enrolment; t_2, 4 weeks post-t_1; t_3, 8 weeks post-t_2; t_4, within 1 month of t_3. BAPAD1, Barriers to Physical Activity in Diabetes—Type 1 scale (23); BGL, blood glucose level; IPAQ-SF, International Physical Activity Questionnaire—Short Form (26); PA, physical activity; PAID-SF, Problem Areas In Diabetes—Short Form (27); WHO-5, 5-item World Health Organization Well-being Index (28).

between 18 and 65 years of age. A total of 86 eligible and consenting participants provided baseline data and attended initial workshops. Of these participants, 81% returned for their booster workshop 4 weeks later. Trial participant baseline characteristics are reported in Table 1. The pilot RCT design was acceptable to participants and feasible to administer. Preliminary evidence suggests theory-driven self-management group education (on the topic of T1D management for PA) is feasible and acceptable to adults living with T1D. We observed small-to-moderate effect sizes in favour of the intervention for overall barriers to PA; FoH as a barrier to PA; self-efficacy for BG management before, during and after PA; diabetes distress; and well-being (18).

Focus group interviews further explored the quantitative acceptability findings, guided by Standards for Reporting Qualitative Research (25). To complement the qualitative assessment of acceptability, we also report data on use of participant resources and the private Facebook group, and on intervention fidelity.

Ethics approval for this study was obtained through Curtin University and State Health Services human research ethics committees.

Sample

Participants were recruited by e-mail from those who did not withdraw from the RCT. Recruitment was open for 6 weeks, at which time there was no further interest. Participants remained blinded to their study arm until the conclusion of the interview.

Data collection methods

Focus groups were conducted in small, face-to-face groups and were approximately 60 minutes in duration. The researchers who conducted the interviews (G.L. and J.B.) were not involved in quantitative data collection and were not known to the research participants. The primary researcher involved in quantitative data collection (M.B.) played a minimal role in the interviews but was present to collect field notes. A semistructured interview guide was used (Supplementary Appendix S1); discussions were audio-recorded, de-identified and transcribed verbatim, using NVivo version 12 (QSR International, Melbourne, Australia). Field notes detailing nonverbal interactions were used to orient audio recordings.

Intervention take-home resources and private Facebook group were evaluated by questionnaire items that asked participants about frequency of use and helpfulness. Facebook activity metrics were also captured directly from the platform (Supplementary Appendix 2).

All intervention and control sessions were video-recorded (with permission) to assess fidelity of facilitator behaviours and content delivered. Intervention facilitation used Social Cognitive Theory (SCT)-informed material and content was guided by the consensus statement from Riddell et al (11), whereas the control was standard care and did not use SCT-informed material (19). Three intervention and 3 control session recordings were randomly selected for review by an experienced coder external to the project and who was familiar with SCT (19). Behaviours and content were coded as either observed or not observed based on the Analysis System for Self-Efficacy Training (26). Behaviour change techniques (BCTs) were coded against the intervention facilitator manual using the BCT Taxonomy Version 1 (27) (see Supplementary Appendix 3 for coding tools).

Data analysis

We used a *staged approach* to data integration, where results of our mixed methods studies have been reported in stages with

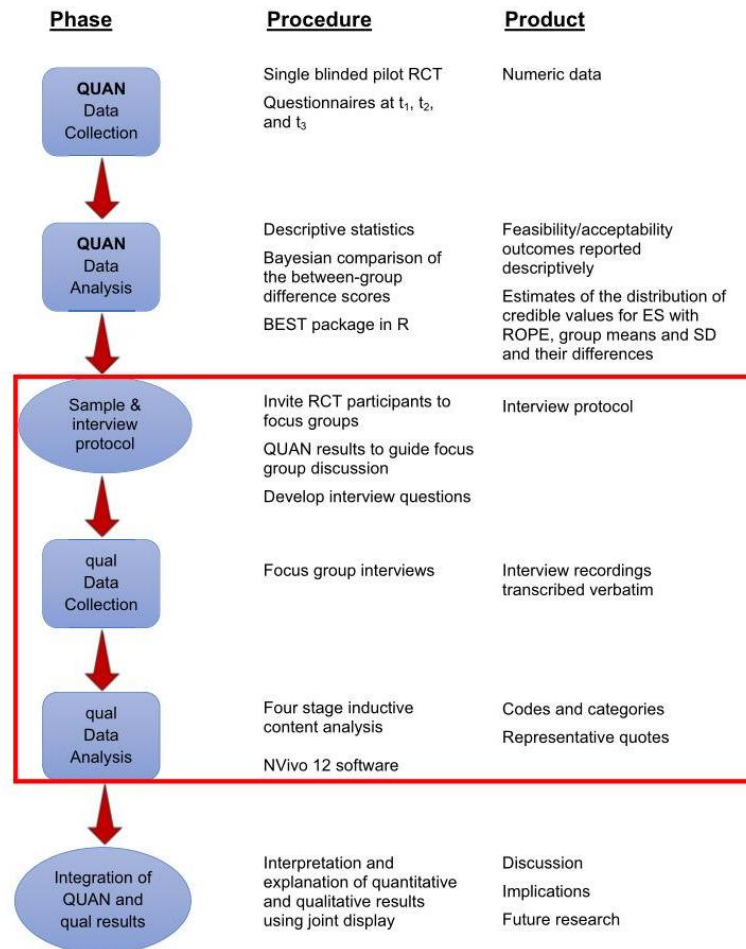| Phase	Procedure	Product
QUAN Data Collection	Single blinded pilot RCT Questionnaires at t_1, t_2, and t_3	Numeric data
QUAN Data Analysis	Descriptive statistics Bayesian comparison of the between-group difference scores BEST package in R	Feasibility/acceptability outcomes reported descriptively Estimates of the distribution of credible values for ES with ROPE, group means and SD and their differences
Sample & interview protocol	Invite RCT participants to focus groups QUAN results to guide focus group discussion Develop interview questions	Interview protocol
qual Data Collection	Focus group interviews	Interview recordings transcribed verbatim
qual Data Analysis	Four stage inductive content analysis NVivo 12 software	Codes and categories Representative quotes
Integration of QUAN and qual results	Interpretation and explanation of quantitative and qualitative results using joint display	Discussion Implications Future research

Figure 2. Visual model of mixed methods, explanatory sequential design. This work describes the highlighted section in greater detail. Time periods: t_1, initial workshops; t_2, booster workshops; t_3, 8 weeks post-t_2. ES, effect size; QUAN, quantitative; qual, qualitative; RCT, randomized controlled trial; ROPE, region of practical equivalence; SD, standard deviation. Adapted from Ivankova et al (23).

qualitative and quantitative data analyzed and published separately (18,28). Focus group participant baseline characteristics, utility of resources and Facebook group data are presented descriptively. Observed key content, facilitator communication skills and facilitator behaviours (fidelity assessment) are reported as a percentage of total possible observations for each selected intervention and control session. The interview transcripts were analyzed using the 4-stage inductive content analysis approach (29). Focus group data were organized by grouping categories under interview question topics that aimed to address specific study objectives. After in-depth data familiarization, 2 researchers (M.B. and G.L.) independently identified "meaning units" and generated codes in an iterative process. Codes were compared and consolidated between the 2 researchers. The original text was reread alongside the meaning units and codes to ensure important text was not missed. Categories were then identified and compiled. To illuminate phenomena more clearly, quantification was used to count (but not rank) categories.

Results

Thirty-four participants were recruited, of whom 21 attended their scheduled focus groups. Interviewed participants had an average age of 46 years; about half were female, and had been living with T1D for an average of 23 years. Focus group participant characteristics closely matched those of the RCT sample and are reported in Table 1.

Acceptability of procedures

Overall study procedure: Four categories emerged from the data: process; flexibility; support; and mode of recruitment. Overwhelmingly, participants reported no problems with study procedures, including registration and attendance, and did not feel obligated. Many appreciated the flexibility of the procedures and found location, time and weekend options convenient: "It was

Table 1
Baseline characteristics of RCT and focus group participants

Baseline characteristics	RCT participants			Focus groups		
	Control	Intervention	All	Control	Intervention	All
Number of groups	8	10	18	3	2	5
Number of participants	47	39	86	12	9	21 *
Number of participants in each group (range)	3–11	2–11	2–11	2–5	4–5	2–5
Females, n (%)	24 (51%)	24 (62%)	48 (56%)	7 (58%)	3 (33%)	10 (48%)
Age, years, mean ± SD	47±11.15	42±11.68	45±11.68	52±8.48	39±8.26	46±10.37
Ancestry (most commonly selected), n (%)						
English	23 (49%)	17 (44%)	40 (47%)	7 (58%)	2 (22%)	9 (43%)
Non-Indigenous Australian	21 (45%)	14 (36%)	35 (41%)	5 (42%)	4 (44%)	9 (43%)
Married/partnered, n (%)	32 (68%)	28 (72%)	60 (70%)	7 (58%)	8 (89%)	15 (71%)
Children in their care, n (%)	22 (47%)	15 (38%)	37 (43%)	4 (33%)	5 (56%)	9 (43%)
Highest educational level, n (%)						
Tertiary	24 (51%)	22 (58%)	46 (54%)	8 (67%)	6 (67%)	14 (67%)
Employed, n (%)	35 (74%)	33 (85%)	68 (79%)	9 (75%)	9 (100%)	18 (86%)
Duration of diabetes, years, mean ± SD	21.42±15.84	19.17±12.2	20.4±14.27	32±16.37	12±8.29	23±16.65
Diabetes management (could select >1), n (%)						
Pump	18 (38%)	13 (33%)	31 (36%)	5 (42%)	3 (33%)	8 (38%)
Multiple daily injections	26 (55%)	23 (59%)	49 (57%)	7 (58%)	6 (67%)	13 (62%)
Continuous glucose monitoring	6 (13%)	9 (23%)	15 (17%)	2 (17%)	3 (33%)	5 (24%)
Flash glucose monitoring	13 (28%)	12 (31%)	25 (29%)	2 (17%)	3 (33%)	5 (24%)
Blood glucose monitoring	29 (62%)	28 (72%)	57 (66%)	8 (67%)	5 (56%)	13 (62%)

RCT, randomized controlled trial; *SD*, standard deviation.
 * Thirty percent of those eligible to participate.

perfect from locationwise. It's always appreciated to have options of where to go" (P001).

Two participants mentioned that finding the time to attend both sessions (initial and booster) was difficult. Participants felt well supported by the facilitator and appreciated the study incentives (gift card and resistance band). Mode of recruitment into the study was varied but most reported hearing about the study through Diabetes WA online media and 3 heard about it from their health professionals and flyers.

Attraction to the study: Categories detailing what attracted participants to the study were: learning more; exercise-specific; criteria; group participation; and research participation. Participants were most commonly attracted to the study to learn more about exercise and/or hypoglycemia relating to exercise. Participants appreciated the program was specific to exercise and involved group participation; for many this is what attracted them to the study:

> The reason it got my attention was because there isn't really any other information available for type 1 and exercise. You can find heaps of information on carb counting and, you know, you can go to a clinic and get advice about that but not necessarily about exercising. So, for me, that's why I wanted to participate. (P007)

Some were attracted to the study through a desire to participate in research and appreciated the broad inclusion and exclusion criteria.

Randomization: Responses relating to randomization led to the formation of the following categories: accepted as a research process; missing-out; and blinding. For most, randomization was not a deterrent and was accepted and understood as a research process. However, some participants did stress that randomization gave them a sense of missing-out or being told incorrect information:

> I think after I attended the first session and I had all the notes and stuff I thought, well, do I even take this seriously? Because, if it's not the real group, and then I am just learning and investing in something that isn't right. (P007)

Beyond speculative remarks, participants did not seem to be aware of the group to which group they were allocated.

Questionnaire: Four categories were formulated based on responses regarding the questionnaire: design issues; interpretation; digital preferred; and technical issues. Many participants conveyed negative feedback relating to the design of the questionnaire, suggesting it was long, repetitive and broad, and they did not like forced-response questions. Participants indicated that interpretation of the questions varied. Some highlighted that their responses were not reflective of what they had learned and that their understanding of questions may have changed over the course of the study:

> The reason why you are not so fearful anymore, for me (it) was because I more clearly understood the mode of exercise and how to respond to those (but this wasn't captured by the questionnaire). (P008)

Some used objective means (personal activity-tracking devices, continuous glucose monitoring) to answer questions, whereas others relied on recall. Despite a small number of participants reporting technical issues with questionnaires administered on tablet devices, digital questionnaires were preferred over paper.

Acceptability of intervention and control

Intervention content: Four categories were formed to describe feedback on the intervention content: program resources; participant enthusiasm; new information; and facilitation and design. Information in the intervention was enlightening and new for participants, and they suggested there is limited existing information and programs with a focus on T1D and PA:

> There was a bit of information there that was ground breaking for me; (it) was the difference in intensity, the effect on your levels from intensity…Not knowing that different types of exercise are having different effects so, um, that just changed my whole thought process about what I am doing and when to do it. (P009).
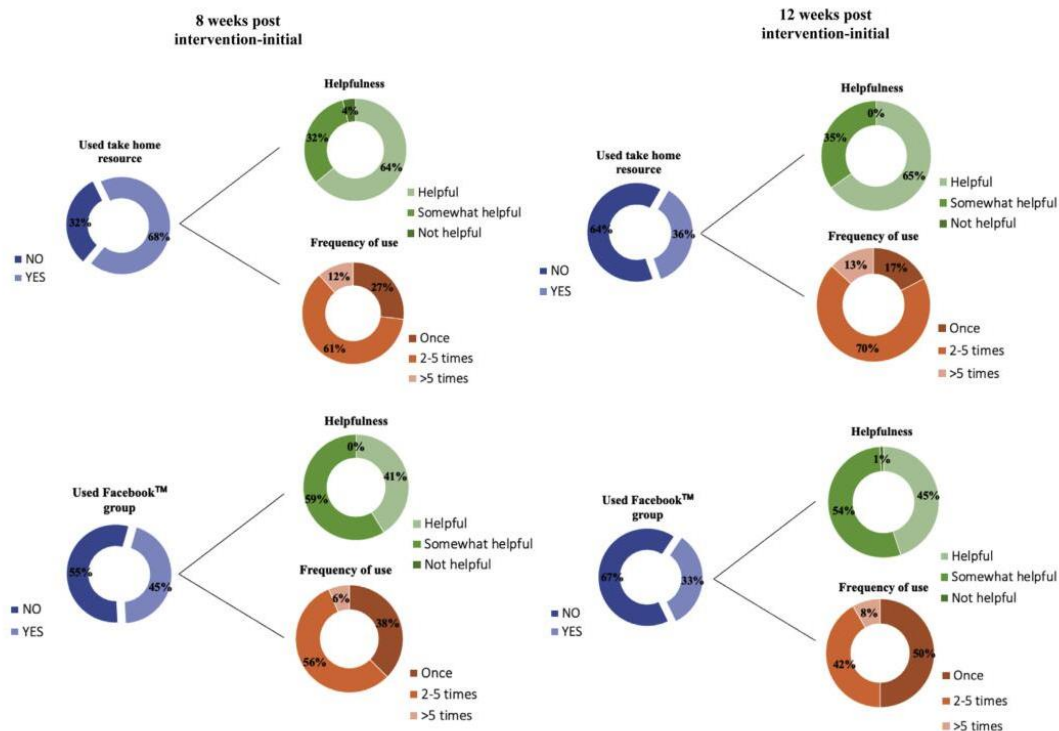
Figure 3. Utilization of intervention resources and Facebook page.

Participants found the program resources and activities helpful in facilitating learning. Feedback relating to the intervention facilitation and design—specifically the length of the intervention—was mixed; some would have liked the intervention to be longer and others stated the length was adequate. Participants were enthusiastic in their overall feedback of the intervention, stating it was "fantastic" (P009), "above expectations" (P003) and was "fun" (P004). The utility of intervention resources is shown in Figure 2.

Control content: Categories representing data relating to control content were: facilitation and design; new/helpful information; not new; and expectations. The facilitation and design of the control was described positively by most participants. Participants appreciated the facilitator showing an interest in PA and were encouraged by the language used. Participants expressed mixed views on the length of the control, some stating they liked the short session, whereas others indicated the session could have been longer. Control focus group participants frequently acknowledged the control contained new and helpful information:

> Previously I thought 30 minutes, 3 times a week, would be okay, but then at the session (I was told) that's just the bare minimum. (P010)

Even so, several stated the session did not offer any new information. Two participants explained they had no expectations going into the program.

Group learning: Both study arms were asked to comment on the group learning and the following categories were formed: group facilitated learning; group interaction; and size matters. Group interaction was viewed by most as a positive experience and some believed it felt less judgemental than one-on-one consults.

Participants of the control and intervention preferred this setting, felt supported by the group and reported that they would attend future group education based on their experience. Some suggested they learned from the group and their experiences:

> I preferred the group setting because it was interesting to hear other people's perspectives…everyone started contributing and you sometimes learnt more from the things other people were saying. (P007)

Two participants representing the control group did not find the group environment beneficial. Many suggested group size matters and felt groups were too small, although some were more comfortable in smaller groups.

Facebook: Two categories were created to reflect data relating to Facebook: online platform supplemental and Facebook not the preferred platform. Participants' were ambivalent toward Facebook, with many explaining they were passive users of the group, whereas others indicated it was an important aspect of the program and used it to share their experience, with one participant suggesting, "the bigger it is, the more benefit it could have" (P006). The second category identifies that Facebook was not the preferred platform as it was difficult for participants to invest in another Facebook group and they did not know anyone in the group, and some preferred not to use the platform. Suggested alternatives included WhatsApp, Facebook Messenger or the use of a program webpage.

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Table 2
Fidelity of intervention and control delivery

	Key content	Communication skills *	Facilitator behaviours *
Intervention initial			
1	93%	100%	89%
2	100%	90%	93%
3	100%	90%	100%
Intervention booster			
1	71%	90%	77%
2	86%	100%	77%
3	100%	100%	90%
Control initial			
1	100%	50% †	NA
2	100%	50% †	NA
3	100%	80% †	NA
Control booster			
1	100%	80% †	NA
2	100%	60% †	NA
3	100%	80% †	NA

NA, not applicable.

Note: Three intervention and control workshop recordings (initial and booster) were randomly selected for coding. The percentages of total possible observations for each selected intervention and control sessions are reported.

* Communication skills (nonjudgemental, nonverbal body language and active listening) and facilitator behaviours aligning with Social Cognitive Theory.

† Lower scores desired in the control.

Quantitative data describing the utility of the Facebook group are reported in Figure 3. A summary of Facebook activity metrics is shown in Supplementary Appendix 2.

Areas to improve—Intervention: Participants offered suggestions to refine the approach, including more examples and case studies to work through, online resources and potentially separating groups for people using pumps vs multiple daily injections. Intervention participants did like having participants with varied physical activity levels being involved as it encouraged role-modelling.

Desired content and approach—Control: Many control participants voiced their desire for content, which in fact was included in the intervention content and approach: information on food; explanation of hypoglycemia; education on how to manage BGLs for exercise; mental health aspects; and more interaction between group members.

Fidelity of intervention delivery: The randomly selected interventions had a mean group size of 4±0 (initial) and 4±0.58 (booster) participants, and the control sessions had a mean group size of 7±2.65 (initial) and 5±1.15 (booster) participants. A summary of fidelity coding results is shown in Table 2, and full coding tools data are provided in Supplementary Appendix 3.

Impact on primary and secondary outcomes

Perceived effect—Intervention: We asked participants if they thought the intervention had an effect on barriers to PA, confidence to manage BGLs and participate in PA, attitude and intentions toward PA, diabetes distress and well-being. We summarized responses with 2 categories: improving outcomes and commending the intervention. Many expressed they had experienced improvements in mental health, fear of hypo- and hyperglycemia as barriers to PA, confidence, actual physical activity participation and a reduction in frequency of hypoglycemia:

> I have got over the fear of not exercising because I am high...and the other way as well, low. (P008)

I had a lot of them (hypos) because I didn't understand what was what. So, now I have only had 2 since I have had the sessions. Two hypos. I used to have 3 to 4 a day. (P003)

Outside of these outcomes, participants commended the intervention, indicating they learned a lot but still need to implement what they learned; they have improved monitoring and recording, improved exercise preparation, tried continuous glucose monitoring and stated that education and knowledge is important for diabetes distress.

Perceived effect—Control: We asked the same questions to the control participants and summarized using the 2 categories: improving outcomes and status quo. Although some participants did mention the session changed their beliefs around hypoglycemia and PA, and increased physical activity participation, most indicated the session had minimal effect (status quo):

> After the session, I wanted to sign up for a gym session, went swimming once and then left it there. So, yeah, I am definitely more motivated, I just need to get onto it. (P010)

What helps? The most frequently suggested components to increase confidence and reduce FoH as a barrier (by both intervention and control participants) were peer support managing and monitoring and a focus on PA. The strongest emphasis was on peer support after the program.

Many participants also noted managing and monitoring BGLs was motivating, provided confidence and helped reduce FoH as a barrier. Participants liked the specific focus on PA, finding this helpful and novel:

> It's not often you get a session that's just about exercise. It's usually crammed in on top of a bunch of other things. (P016)

Discussion

The aim of this study was to provide a process evaluation of a self-management group education program to reduce fear of hypoglycemia as a barrier to physical activity in people living with T1D; we used focus group interviews, and assessed intervention fidelity and resource utility. Most aspects of the study procedures were widely accepted and group education was acceptable and preferred. Fidelity assessment confirmed the intervention was delivered reliably with behaviours and communication skills consistent with SCT (19).

Our recruitment strategy relied heavily upon the support organization's (Diabetes WA) media platforms. Therefore, it was not surprising to hear focus group participants reveal the most common mode of recruitment was via Diabetes WA media (e-mail, e-newsletters, website, social media). Access to these media channels was crucial to the success of the study's recruitment strategy. Although we aimed to appeal to those who were experiencing hypoglycemia or FoH as barriers to PA, participants not identifying with these barriers were still drawn to the study. The recruitment strategy attracted individuals who were interested in a program devoted to physical activity and who were eager to learn how to manage BGLs for exercise. This response supports the demand for an evidence-informed, self-management education program on this topic from those motivated to improve exercise participation, but future recruitment strategies should be adjusted to target a less active cohort (30).

We asked about participants' experience with registration, randomization and completion of questionnaires. They reported few issues with the process of registration, screening, consent and attendance. Many found the times and locations convenient, and they liked the flexibility this provided. It is possible, however, that accommodating participants' preferences by having multiple time, date and location options resulted in small workshop groups (18). Future trials should consider extending the intervention delivery phase to allow groups to fill before they commence and hence still accommodate participants' preferences.

The process of randomization was described in detail both verbally and in the Participant Information Statement; however, feedback suggests it was not clear enough to appease all participants' concerns, and perhaps deterred people from registering an interest in the first instance. A review of randomized clinical trials showed that the concept of randomization remains difficult for participants to conceptualize and often the rationale for randomization needs to be explained in greater detail (31). In addition to existing processes, written and verbal participant information relating to randomization needs to be emphasized in reassuring future participants that they will not miss out on an effective intervention nor receive incorrect or misleading information, regardless of their allocation.

A number of negative comments were raised in relation to the questionnaire design. Issues relating to questionnaire length (45 items), item repetitiveness and responder fatigue were raised. The extensive item list was due to the use of established multi-item scales; future studies should explain to participants why multi-item scales are needed to test validity and reliability of questionnaire scores. Improvement in knowledge, positive changes to self-management strategies and change in activity type were all highlighted by participants as important outcomes, yet participants felt they were not adequately captured by the questionnaire. Although these items were not measured, we believe self-efficacy is a more meaningful outcome and predictor of positive self-care behaviours (32). Possessing knowledge and skill does not imply someone is capable or confident in performing the task, whereas self-efficacy is the belief in being capable of *applying* knowledge and skill (32). Furthermore, focus group data have identified benefits beyond what was captured in the questionnaire, such as those detailed under *commending the intervention* category.

Participants shared that the intervention content was new to them. Visual aids were used alongside systematic processing (Dual Process Theory) (20) to discern complex metabolic and endocrine responses to PA. Participants reported this to be a helpful and illuminating section of intervention. This feedback is consistent with findings from the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed collaborative, which used Dual Process Theory with visual aids to support learning around BG regulation in adults with type 2 diabetes (33,34). Quantitative analysis of take-home resources revealed that, although the overall use of take-home resources dropped over the course of the intervention, those using them found them helpful (Figure 2). The utility and helpfulness of participant resources may be improved by providing portable take-home resources via an online platform or phone app, as suggested by focus group participants.

Group education on PA in this population has not been researched or documented in Australia, so it was important to establish the acceptability of this approach in a pilot phase. The findings relating to participants' positive experience of group education is consistent with qualitative findings of the EXTOD Education Programme Development team in the United Kingdom and supports our approach to diabetes education on this complex topic (30). It also corroborates the quantitative findings showing that PA group education is acceptable and preferred by adults living with T1D (18).

Consistent with quantitative findings, intervention participants reported a perceived reduction in "diabetes-specific" barriers to PA (including FoH and hyperglycemia), improved confidence in managing BGLs for PA and improved mental health (18). Although these perceptions of intervention effects are promising and corroborate the quantitative findings, they require further investigation in a definitive trial.

Although intervention participants did not advocate for altering the intervention content, they did articulate some suggestions to refine the intervention approach, suggesting allocating more time for case studies and personal examples. There was also a strong belief that ongoing peer support would be beneficial. Allowing more time to work through examples and problem-solve is likely to strengthen mastery experience, whereas providing greater opportunities for organized peer support after the intervention is likely to encourage further role-modelling; both mastery experiences and role-modelling are key sources of self-efficacy (26,35). The Facebook component of the intervention was intended to offer ongoing topic-specific peer support. We postulate this adjunct component would consolidate learning and provide extended, meaningful opportunities for role-modelling and skills mastery (35). However, qualitative and quantitative assessments (Supplementary Appendix 3 and Figure 2) indicate that very few utilized the Facebook group; those who did had mixed attitudes toward the group, and many were passive users. A review of diabetes online communities reported mixed findings relating to the benefit of online communities to those who were passive users (36). To impact PA behaviour change, future iterations of the intervention should involve opportunities for intensive, face-to-face, peer-led PA sessions in addition to the existing program-specific diabetes online community following the group education component. Suggested alternative online platforms, such as WhatsApp, Facebook Messenger or the use of a program webpage, may also be considered.

Fidelity assessments examined *what* was delivered, *how* it was delivered and whether the intervention was consistent with the underlying SCT (19,37). Content, communication skills and facilitator behaviours observed throughout the 3 recorded sessions of the initial workshop were consistent between intervention groups and consistent with underlying theory. Slightly more variation in content and behaviour was observed in the "intervention-booster" sessions, particularly in Section 3: Conclusions. Although precise adherence to intervention manuals can reflect an inflexible and unresponsive delivery style, the inconsistencies or "drift" observed in Section 3 was unintentional and we believe it arose from time-restraint barriers (38). Future iterations of the intervention should consider either greater time allocation to Section 3, or extending the duration of the booster session. Extending this session is also likely to allow more time for sharing personal experience and problem-solving group scenarios—a previously discussed suggestion from participants.

Fidelity assessment of control sessions revealed consistent delivery of content between control groups. We intended for the control to be delivered in a didactic style, minimizing social learning, as these features were thought to reflect current standard care. However, some control sessions were assessed as displaying up to 80% of the listed communication skills consistent with SCT (19). The same facilitator (M.B.) delivered both control and intervention sessions. Although this may have minimized variability in delivery, for a facilitator trained in Social Cognitive Theory, it is difficult to display behaviours that are void of those to which they are trained and accustomed. Furthermore, despite aiming to replicate information available in standard care, our control focus group participants echoed sentiments of our intervention participants—that the information provided was new and helpful. Baseline knowledge of PA management in "standard care" may be lower

than we anticipated, and hence, although acceptable to participants, the information contained in the control will be revised to better reflect standard care. A passive rather than active control may be considered in future trials.

Limitations

Generalizability of our qualitative findings are limited due to self-selection bias (39); we recruited participants who were motivated to exercise more by signing up for the RCT. Although the primary researcher involved in quantitative data collection (M.B.) played a minimal role in the focus group interviews, her presence during the interviews may have introduced social desirability bias (40). We countered this by reassuring participants they could give honest responses without jeopardizing their relationship with the researchers or Diabetes WA. Collecting data from multiple sources also aimed to reduce this form of bias.

In conclusion, a future definitive evaluation of Type 1 TACTICS for Exercise should utilize a blinded RCT study design and prioritize recruitment using existing local diabetes databases to maximize participant uptake. Participant Information Statements need to detail more clearly the process of blinded randomization to ensure participants have a better understanding of the process. Control participants indicate that even basic information on PA guidelines and hypoglycemia risk are not currently being provided or accessed. As such, alterations to the control may be required to better reflect local standard care. Our qualitative findings promote group education as an acceptable and preferred method of education on this topic. Further peer support should also be incorporated when determining the utility of Type 1 TACTICS for Exercise in improving PA participation along with objective assessment of exercise via activity trackers.

Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Diabetes* at www. canadianjournalofdiabetes.com.

Acknowledgments

Author Disclosures

M.B. is an employee of Diabetes WA, but the organization had no influence on the interpretation or reporting of results beyond consumer group participation. No other authors have any conflicts of interest to declare.

Author Contributions

M.B. conceived and designed the study including the intervention, delivered the intervention, analysed and interpreted the data, was present for qualitative data collection and drafted the manuscript. J.B., G.L. and N.N. contributed to study design including the intervention, qualitative data collection, data interpretation and drafting/revision of manuscript.

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Appendix C Publication Appendix

The following appendix includes supplements of the publication presented above. Online versions are also available at www.canadianjournalofdiabetes.com.

Supplementary Appendix 1

Focus Group Question Guide

Focus group question guide	Probing questions
What attracted you to the study?	What was the main feature of the program that grabbed your attention and motivated you to register?
	Where did you hear about the study?
How did you find the process from, registering your interest to attending your first session?	What made it easy/hard for you to attend part 1 and part 2?
Did you understand the process of randomisation and its implications?	Did you mind being randomly allocated to a group?
What did you think of the questionnaire?	Positives and negatives about the questionnaires?
	Would you prefer paper or tablets? Why?
Was there anything you wanted to say that the questionnaires didn't capture?	Did you find the questionnaire was worded in a logical and easy to complete format? If not what aspects of the questionnaire could be improved?
	Where there any questions you found confusing?
	Were there positives or negatives you experienced that were not captured by the questionnaire?
What did you think about the content of part 1 and part 2?	Did you feel that the content of the program met your expectations?
	What did you think of the length of part 1 and part 2?
	Was the information contained in part 1/part 2 available to you elsewhere?
	Where do you usually get help/information from to assist you in managing type 1 diabetes?
Do you feel that the group setting helped or hindered you?	Do you feel that the workshop/group setting was an appropriate format for education on this topic?
	Have your beliefs about attending a group education workshop changed since your participation?

Focus group question guide	Probing questions
Facebook group (intervention only) - Why didn't some people use it?	Would another forum be more accessible/useful?
Since attending the workshops have your beliefs of hypoglycaemia and physical activity changed - in what way?	What impact did your workshop have on any fear of hypoglycaemia as a barrier that you may experience?
Consider your thoughts about physical activity prior to attending the group workshop and after attendance. Do you believe that the use of the group setting has had an effect on attitudes, intentions, participation and or confidence towards physical activity, well-being, or diabetes distress?	
Would you recommend this program to others? Why?	
Were there any topics that you would have like to have discussed?	
What would help you do more physical activity?	
What would help you overcome fear of hypoglycaemia as a barrier to physical activity?	
What would help you become more confident with managing blood glucose levels before, during and after physical activity?	
For those who visited their diabetes health professionals during the study, was physical activity discussed?	
Does anyone here use an activity tracking device to monitor their physical activity? Thoughts?	

Supplementary Appendix 2

Facebook Activity Metrics

Facebook™ activity (6/5/2019 – 20/05/2020)	Metrics
Number of members (excluding moderators)	23 (59% of intervention participants)
Number of posts from moderators	34 (55% of total posts)
Number of posts from participants	28 (45% of total posts)
Number of individual participant contributors (new posts)	7 (30% of total members)
Number of individual participant contributors (comments)	9 (39% of total members)
Average number of reactions per post ±SD	2.82 ±2.17
Average number of comments per post ±SD	3.47 ±5.07
Average number of contributors to each post ±SD	1.58 ±1.59
Each post seen by (mean number of participants) ±SD	21.29 ±1.95

Supplementary Appendix 3

Fidelity Assessment Tool – INTERVENTION Part I

Assessor/coder	Workshop ID
SM	1 – Brown 2 – Red 3 – Blue

Review Key

The tools below have been used whilst viewing the recording of the education session to observe the use of facilitator behaviours that are consistent with Social Cognitive Theory.

N	Not Observed	These behaviours were **NOT OBSERVED**
Y	Observed	These behaviours were **OBSERVED**
N/A	Not Applicable	Listed behaviour was not applicable to the situation

Key Content	Y/N			
	Con 1	Con 2	Con 3	Total
Review of physical activity recommendations for people living with type 1 diabetes	Y	Y	Y	3
Progressing physical activity - FIT	Y	Y	Y	3
Hypoglycaemia treatment	Y	Y	Y	3
Resources and onward referral	Y	Y	Y	3
Total (/4)	4	4	4	

Communication Skills

	Desired Behaviour	Supporting Behaviours Observed	Y/N			
			Con 1	Con 2	Con 3	Total
Non-judgemental	Facilitator avoids judging participant choices and beliefs	The facilitator uses phrases such as 'it's your choice', 'it's your decision'	Y	Y	Y	3
		The facilitator reinforces that there is not a good or bad choice	Y	Y	Y	3
		Using non-judgemental door openers eg. 'what do you find the hardest part of managing your condition'	N	N	N	0
		The facilitator encourages participants to draw from their own knowledge and experience to make their own decisions	Y	Y	Y	3
Non-verbal body language	Facilitator uses non-verbal body language to convey interest and empathy	The facilitator maintains eye contact at a comfortable level	Y	Y	Y	3
		The facilitator has an open stance, facing the group with relaxed posture	Y	Y	Y	3
		The facilitator uses nodding of the head and facial expressions appropriately	Y	Y	Y	3
Active Listening	Facilitator uses active listening skills to convey that they have heard what the participant has to say	Clarification – 'could you tell me a little more about that'	N	N	N	0
		Paraphrasing – 'If I'm hearing you correctly…,' "Are you saying that…'	Y	N	Y	2
		Reflection – 'it sounds like…', 'I get the impression that…..	Y	N	Y	2
Total (/10)			8	6	8	

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Section 1: Introduction

Key Content	Int 1	Int 2	Int 3	Total
Burning questions elicited from the group	Y	Y	Y	3
Physical activity recommendations discussion – highlights the importance of any activity is better than none	Y	Y	Y	3
Barriers and some solutions discussion and flipchart completed	Y	Y	Y	3
Total (/3)	3	3	3	

Behaviour		Opportunities to demonstrate behaviour	Int 1	Int 2	Int 3	Total	Behaviour Change Technique
Skills Mastery	Self-Reflection	Encouraging participants to share experience of participating in physical activity and their beliefs surrounding how much physical activity is required	Y	Y	Y	3	1.2 Problem solving 5.1 Information about health consequences
Verbal Persuasion	Elicitation of knowledge	Facilitator actively encourages participants to share what they already know about the topic, even if it is incorrect.	Y	Y	Y	3	6.2 Social comparison
		When incorrect knowledge is elicited, it is explored with the group	N	Y	Y	2	
		Barriers discussed during the session, are used to elicit strategies for planning for obstacles	Y	Y	Y	3	
		Facilitator only gives explanation when it is clear that none of the participants know the answer	Y	Y	Y	3	
	Positive Feedback	Encourages all participants to talk about what they already know and avoids letting one person dominate – gives everyone the opportunity to feel good that they knew something	Y	Y	Y	3	
		Facilitator asks participants what positive effects they might expect from participating in physical activity	Y	Y	Y	3	
Total (/7)			6	7	7		3

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Section 2: Carbohydrate metobolism

Key Content	Y/N			
	Int 1	Int 2	Int 3	Total
Reviews CHO digestion and what effect exercise has on this process for people living with and without type 1 diabetes	Y	Y	Y	3
Highlights how hypoglycaemia may occur with physical activity	Y	Y	Y	3
Explores the physical and psychological impact of hypoglycaemia	Y	Y	Y	3
Hypoglycaemia management/treatment reviewed	N	Y	Y	2
Explores hyperglycaemia and how this occurs – ketones and DKA discussed	Y	Y	Y	3
Physical activity intensity, type and duration of activity are discussed in relation to their effect on blood glucose levels	Y	Y	Y	3
Total (/6)	5	6	6	

Behaviour		Opportunities to demonstrate behaviour	Y/N				Behaviour Change Technique
			Int 1	Int 2	Int 3	Total	
Skills Mastery	Self-Reflection	Encourages participants to share experience of participating in physical activity and their beliefs surrounding how much physical activity is required	Y	Y	Y	3	5.1 Information about health consequences 6.2 Social comparison 16.3 Vicarious consequences
Verbal Persuasion	Elicitation of knowledge	Facilitator actively encourages participants to share what they already know about the topic, even if it is incorrect.	Y	Y	Y	3	
		When incorrect knowledge is elicited, it is explored with the group	Y	Y	Y	3	
		Facilitator uses systematic processing to draw knowledge of diabetes physiology from participants.	Y	Y	Y	3	
		Barriers discussed during the session are used to elicit strategies for planning for obstacles	Y	Y	Y	3	
		Facilitator only gives explanation when it is clear that none of the participants know the answer	Y	Y	Y	3	

	Positive Feedback	Encourages all participants to talk about what they already know and avoids letting one person dominate – give everyone the opportunity to feel good that they knew something	Y	Y	Y	3	
Physical and Emotional Management	Emotion Management	Facilitator encourages participants to express any emotions they have associated with hypoglycaemia	Y	Y	Y	3	
	Physical Symptoms	The facilitator enables participants to discuss their personal beliefs/experiences regarding hypoglycaemia	Y	Y	Y	3	
Total (/9)			9	9	9		3

Section 3: Preparing for exercise

Key Content	Y/N			
	Int 1	Int 2	Int 3	Total
Five factors to consider before participating on physical activity - BFITT	Y	Y	Y	3
Five factors to consider when physical activity is NOT recommended - STUCK	Y	Y	Y	3
Total (/2)	2	2	2	

Behaviour		Opportunities to demonstrate behaviour	Y/N				Behaviour Change Technique
			Int 1	Int 2	Int 3	Total	
Verbal Persuasion	Elicitation of knowledge	Facilitator actively encourages participants to share what they already know about the topic, even if it is incorrect.	Y	Y	Y	3	11.3 Conserving mental resources
		When incorrect knowledge is elicited, it is explored with the group	Y	N/A	Y	2/2	16.3 Vicarious consequences
		Facilitator uses systematic processing to draw knowledge from participants surrounding what factors may influence blood glucose levels for exercise	Y	Y	Y	3	
		Facilitator only gives explanation when it is clear that none of the participants know the answer	Y	Y	Y	3	
Skills Mastery	Self-Reflection	Encourages participants to share experience of participating in physical activity and reflection on what they have considered in preparing for exercise in the past.	Y	Y	Y	3	
Total (/5)			5	4/4	5		2

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Section 4: Blood glucose levels

Key Content	Y/N			
	Int 1	Int 2	Int 3	Total
Reviews different monitoring options – BGM, Flash and CGM	Y	Y	Y	3
Optimal times to monitor are reviewed	Y	Y	Y	3
BG targets discussion for different situations	Y	Y	Y	3
Introduce concepts that could be manipulated to change BGLs – insulin and carbohydrate	Y	Y	Y	3
Total (/4)	4	4	4	

Behaviour		Opportunities to demonstrate behaviour	Y/N				Behaviour Change Technique
			Int 1	Int 2	Int 3	Total	
Verbal Persuasion	Elicitation of knowledge	Facilitator actively encourages participants to share what they already know about the blood glucose levels, even if it is incorrect.	Y	Y	Y	3	6.2 Social comparison 8.6 Generalisation of target behaviour 11.3 Conserving mental resources 15.3 Focus on past success 16.3 Vicarious consequences
		When incorrect knowledge is elicited, it is explored with the group	Y	Y	Y	3	
		Facilitator only gives explanation when it is clear that none of the participants know the answer	Y	Y	Y	3	
	Positive Feedback	Encourages all participants to talk about what they already know and avoids letting one person dominate – give everyone the opportunity to feel good that they knew something	Y	Y	Y	3	
Skills Mastery	Self-Reflection	Encouraging participants to share their experience of monitoring and reflection on what has worked for them in the past	Y	Y	Y	3	
Total (/5)			5	5	5		5

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Section 5: Carbohydrate intake

Key Content	Y/N			
	Int 1	Int 2	Int 3	Total
CHO as a fuel source and its importance in exercise performance	Y	Y	Y	3
Review of what factors may influence how much CHO we need - BFITT	Y	Y	Y	3
Glycogen storage and its importance to exercise and prevention of hypoglycaemia	Y	Y	Y	3
CHO recommendations 1-4 hours before, immediately before, during and after physical activity	Y	Y	Y	3
Highlight the importance of this strategy for 'unplanned' exercise	N	Y	N/A	1/2
Glycaemic index is briefly discussed	Y	Y	N/A	2/2
CHO as a strategy to not only fuel exercise but to prevent and treat hypoglycaemia	Y	Y	N/A	2/2
Total (/7)	6	7	4/4	

	Behaviour	Opportunities to demonstrate behaviour	Y/N				Behaviour Change Technique
			Int 1	Int 2	Int 3	Total	
Skills Mastery	Self-Reflection	Encourages self-reflection to encourage participants to talk about their current knowledge and experience when it comes to using CHO/Insulin as strategies to manage BGLs	Y	Y	N/A*	2/2	4.1 Instruction on how to perform the behaviour
	Successful Trial	Facilitator encourages participants to try use CHO strategies in the 'Timeline' activity	Y	Y	N/A*	2/2	4.2 Information about antecedents
	Facilitating Pro-Active Self	Facilitator encourages discussion of CHO strategies that participants can use to manage BGLs	Y	Y	Y	3	6.1 Demonstration of the behaviour
		Facilitator encourages participants to identify other resources they could use in the future to find out more about CHO counting	Y	N	N/A*	1/2	6.2 Social comparison
Role Modelling	Group Solving	Facilitator asks participants to problem solve how they might be able to identify CHO and how to use CHO/insulin in managing BGLs	Y	Y	N/A*	2/2	8.1 Behaviour practice/rehearsal 8.7 Graded tasks
	Sharing Obstacles	Facilitator encourages participants to share their experiences trying to use CHO and the barriers they have encountered in using this as a strategy	Y	Y	N/A*	2/2	9.3 Comparative imaging of future outcomes
	Competent Other	Facilitator encourages participants to share how they have overcome barriers to using CHO as a strategy	N	Y	N/A*	1/2	11.3 Conserving mental resources

		Facilitator encourages participants to come up with their own solutions to problems using CHO as a strategy	N	Y	N/A*	1/2	15.3 Focus on past success 16.3 Vicarious consequences
Total (/8)			6	7	N/A*		10

*Only half of intervention 3 - initial was coded due to technical issues with the recording. The coder outlined delivery to this point was consistent with Social Cognitive Theory

Section 6: Insulin

Key Content	Y/N			
	Int 1	Int 2	Int 3	Total
Review of what factors may influence how much insulin we need - BFITT	Y	Y	N/A	2/2
Insulin action profiles reviewed and linked to how this would impact on decisions surrounding exercise management	Y	Y	N/A	2/2
Options to minimise risk of hypoglycaemia – insulin adjustment, moving meal and bolus before exercise, moving exercise	Y	Y	N/A	2/2
Nocturnal hypoglycaemia and how insulin adjustment (basal) may be a factor	Y	Y	N/A	2/2
Guidelines for safe insulin titration are discussed for both MDI and pumps (if someone on pump)	Y	Y	N/A	2/2
Total (/5)	5	5	N/A	

Behaviour		Opportunities to demonstrate behaviour	Y/N				Behaviour Change Technique
			Int 1	Int 2	Int 3	Total	
Skills Mastery	Self-Reflection	Encourages self-reflection to encourage participants to talk about their current knowledge and experience when it comes to using CHO/Insulin as strategies to manage BGLs	Y	Y	N/A*	2/2	4.1 Instruction on how to perform the behaviour
	Successful Trial	Facilitator encourages participants to try use insulin strategies in the 'Timeline' activity	Y	Y	N/A*	2/2	4.2 Information about antecedents
	Facilitating Pro-Active Self	Facilitator encourages discussion of insulin strategies that participants can use to manage BGLs	Y	Y	N/A*	2/2	6.1 Demonstration of the behaviour
		Facilitator encourages participants to identify other resources they could use in the future to find out more about insulin adjustment	Y	N	N/A*	1/2	6.2 Social comparison
Role Modelling	Group Solving	Facilitator asks participants to problem solve how they might be able use CHO/insulin in managing BGLs	Y	Y	N/A*	2/2	8.1 Behaviour practice/rehearsal
	Sharing Obstacles	Facilitator encourages participants to share their experiences trying to use insulin and the barriers they have encountered in using this as a strategy	Y	Y	N/A*	2/2	8.7 Graded tasks
	Competent Other	Facilitator encourages participants to share how they have overcome barriers to using insulin as a strategy	Y	Y	N/A*	2/2	9.3 Comparative imaging of future outcomes
		Facilitator encourages participants to come up with their own solutions to problems using insulin as a strategy	Y	Y	N/A*	2/2	11.3 Conserving mental resources
Total (/8)			8	7	N/A*		15.3 Focus on past success
							16.3 Vicarious consequences
							10

*Only half of intervention 3 - initial was coded due to technical issues with the recording. The coder outlined delivery to this point was consistent with Social Cognitive Theory

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Goal setting

Key Content		Y/N			
		Int 1	Int 2	Int 3	Total
Introduction of exercise diary		Y	Y	N/A	2/2
Goal setting explained step by step		Y	Y	N/A	2/2
Total (/2)		2	2	N/A	

	Behaviour	Opportunities to demonstrate behaviour	Y/N				Behaviour Change Technique
			Int 1	Int 2	Int 3	Total	
Skills Mastery	Self-reflection	Encouraging participants to reflect on their prior experience of action planning/goal setting	N	Y	N/A*	1/2	1.1 Goal setting (behaviour)
	Successful Trial	Facilitator encourages participants to work independently to complete an action plan/goal	Y	Y	N/A*	2/2	1.2 Problem solving
							1.3 Goal setting (outcome)
	Facilitating Pro-Active Self	Facilitator encourages participants to think about which strategy they can apply from the session that would enhance their own diabetes self-management	Y	Y	N/A*	2/2	1.4 Action planning
							2.3 Self-monitoring of behaviour
Verbal Persuasion	Positive Feedback	Facilitator asks participants what positive outcomes they might expect from using new strategies and PA as part of their diabetes self-management	N	N	N/A*	0/2	3.1 Social support (unspecified)
							3.3 Social support (emotional)
	Planning for Obstacles	The facilitator emphasises the importance of goal setting.	Y	Y	N/A*	2/2	4.2 Information about antecedents
							5.4 Monitoring of emotional consequences
							15.1 Verbal persuasion about capability
Total (/5)			3	4	N/A*		10

*Only half of intervention 3 - initial was coded due to technical issues with the recording. The coder outlined delivery to this point was consistent with Social Cognitive Theory

Fidelity Assessment Tool – INTERVENTION Part II

Assessor/coder	Workshop ID
SM	1 – Brown 2 – Red 3 – Blue

Review Key

The tools below have been used whilst viewing the recording of the education session to observe the use of facilitator behaviours that are consistent with Social Learning Theory.

N	Not Observed	These behaviours were **NOT OBSERVED**
Y	Observed	These behaviours were **OBSERVED**
N/A	Not Applicable	Listed behaviour was not applicable to the situation

Communication Skills

	Desired Behaviour	Supporting Behaviours Observed	Y/N			
			Int 1	Int 2	Int 3	Total
Non-judgemental	Facilitator avoids judging participant choices and beliefs	The facilitator uses phrases such as 'it's your choice', 'it's your decision'	Y	Y	Y	3
		The facilitator reinforces that there is not a good or bad choice	Y	Y	Y	3
		Using non-judgemental door openers e.g. 'what do you find the hardest part of managing your condition'	Y	Y	Y	3
		The facilitator encourages participants to draw from their own knowledge and experience to make their own decisions	Y	Y	Y	3
Non-verbal body language	Facilitator uses non-verbal body language to convey interest and empathy	The facilitator maintains eye contact at a comfortable level	Y	Y	Y	3
		The facilitator has an open stance, facing the group with relaxed posture	Y	Y	Y	3
		The facilitator uses nodding of the head and facial expressions appropriately	Y	Y	Y	3
Active Listening	Facilitator uses active listening skills to convey that they have heard what the participant has to say	Clarification – 'could you tell me a little more about that'	N	Y	Y	2
		Paraphrasing – 'If I'm hearing you correctly…,' "Are you saying that…'	Y	Y	Y	3
		Reflection – 'it sounds like…', 'I get the impression that…..	Y	Y	Y	3
Total (/10)			9	10	10	

Section 1: Introduction

Key Content	Y/N			
	Int 1	Int 2	Int 3	Total
Review of burning questions from part 1	N	Y	Y	2
Reflect on goal from four weeks ago	Y	Y	Y	3
Total (/2)	1	2	2	

Behaviour		Opportunities to demonstrate behaviour	Y/N				Behaviour Change Technique
			Int 1	Int 2	Int 3	Total	
Verbal Persuasion	Elicitation of knowledge	Facilitator actively encourages participants to share what they already know about the topic, even if it is incorrect.	N	N	N	0	5.4 Monitoring of emotional consequences
		When incorrect knowledge is elicited, it is explored with the group	N/A	N/A	N/A	N/A	6.2 Social comparison
	Positive Feedback	Encourages all participants to talk about what they already know and avoids letting one person dominate – give everyone the opportunity to feel good that they knew something	Y	Y	Y	3	15.1 Verbal persuasion about capability
Role Modelling	Sharing Obstacles	Facilitator gives participants opportunities to discuss any problems they had completing the goal setting/progress in achieving their goal and explores any lack of confidence	Y	Y	Y	3	
Total (/3)			2	2	2		3

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Section 2: Scenarios

Key Content	Y/N			
	Int 1	Int 2	Int 3	Total
Discuss scenarios, problems and successes over the last four weeks	Y	Y	Y	3
Work through scenarios on the board and individually (if suitable)	Y	Y	Y	3
Total (/2)	2	2	2	

	Behaviour	Opportunities to demonstrate behaviour	Y/N				Behaviour Change Technique
			Int 1	Int 2	Int 3	Total	
Skills Mastery	Self-Reflection	Encourages participants to share experience of participating in physical activity and their beliefs surrounding how and why some strategies did or did not work	Y	Y	Y	3	3.1 Social support (unspecified)
	Successful Trial	Facilitator encourages participants to try use learned strategies in the 'Timeline' activity	Y	Y	Y	3	3.3 Social support (emotional)
	Facilitating Pro-Active Self	Facilitator encourages discussion of strategies that participants can use to manage BGLs	Y	Y	Y	3	4.2 Information about antecedents
		Facilitator encourages participants to identify other resources they could use in the future to further their knowledge	Y	Y	Y	3	5.4 Monitoring of emotional consequences
Verbal Persuasion	Elicitation of knowledge	Facilitator actively encourages participants to share what they already know about the topic, even if it is incorrect.	Y	Y	Y	3	6.1 Demonstration of the behaviour
		When incorrect knowledge is elicited, it is explored with the group	Y	Y	N/A	2/2	6.2 Social comparison
		Facilitator uses systematic processing to draw knowledge of diabetes physiology from participants.	Y	Y	Y	3	8.1 Behaviour practice/rehearsal
		Barriers discussed during the session are used to elicit strategies for planning obstacles	Y	Y	Y	3	11.3 Conserving mental resources
		Facilitator only gives explanation when it is clear that none of the participants know the answer	Y	Y	Y	3	15.3 Focus on past success
							16.3 Vicarious consequences

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	Positive Feedback	Encourages all participants to talk about what they already know and avoids letting one person dominate – give everyone the opportunity to feel good that they knew something	Y	Y	Y	3	
Physical and Emotional Management	Emotion Management	Facilitator encourages participants to express any emotions they have associated with hypoglycaemia (if this comes up)	Y	Y	N	2	
	Physical Symptoms	The facilitator enables participants to discuss their personal beliefs/experiences regarding hypoglycaemia (if this comes up)	Y	Y	Y	3	
Total (/12)			12	12	10/11		10

Section 3: Conclusions (including goal setting)

Key Content	Y/N			
	Int 1	Int 2	Int 3	Total
Revisit barriers to physical activity from four weeks ago	Y	Y	Y	3
Revisit burning questions from four weeks ago	Y	Y	Y	3
Revisit goal setting	N	N	Y	1
Total (/3)	2	2	3	

	Behaviour	Opportunities to demonstrate behaviour	Y/N				Behaviour Change Technique
			Int 1	Int 2	Int 3	Total	
Skills Mastery	Self-reflection	Encourages participants to reflect on their prior experience of action planning	N	N	Y	1	1.1 Goal setting (outcome) 1.2 Problem solving
	Successful Trial	Facilitator encourages participants to complete goal setting sheet	N	N	Y	1	1.3 Goal setting (behaviour)
	Facilitating Pro-Active Self	Facilitator encourages participants to think about which strategy they can apply from the session that would enhance their own diabetes self-management	N	N	Y	1	1.4 Action planning 2.3 Self-monitoring of behaviour
Role Modelling	Competent Other	Facilitator encourages participants to share how they are going to overcome barriers to managing BGLs for PA and put new skills into practice.	Y	Y	Y	3	3.1 Social support (unspecified)
		The facilitator avoids giving their own solutions.	Y	Y	Y	3	
Verbal Persuasion	Planning for Obstacles	The facilitator emphasises the importance of goal setting.	N	N	Y	1	3.3 Social support (emotional) 4.2 Information about antecedents
		Barriers discussed during the session are used to elicit strategies for planning for obstacles.	Y	Y	Y	3	8.7 Graded tasks 15.1 Verbal persuasion about capability
Total (/7)			3	3	7		10

Fidelity Assessment Tool – Control Part I

Assessor/coder	Workshop ID
SM	1 – Red 2 – Orange 3 – Pink

Review Key

The tools below have been used whilst viewing the recording of the education session to observe the use of facilitator behaviours.

N	Not Observed	These behaviours were **NOT OBSERVED**
Y	Observed	These behaviours were **OBSERVED**

Key Content	Y/N			
	Con 1	Con 2	Con 3	Total
Benefits of physical activity	Y	Y	Y	3
Physical activity recommendations for people living with type 1 diabetes	Y	Y	Y	3
Moderate versus vigorous intensity physical activity	Y	Y	Y	3
Barriers and solutions to physical activity	Y	Y	Y	3
Hypoglycaemia signs and symptoms	Y	Y	Y	3
Hypoglycaemia treatment	Y	Y	Y	3
Total (/6)	6	6	6	

Communication Skills

	Desired Behaviour	Supporting Behaviours Observed	Y/N			
			Con 1	Con 2	Con 3	Total
Non-judgemental	Facilitator avoids judging participant choices and beliefs	The facilitator uses phrases such as 'it's your choice', 'it's your decision'	Y	Y	Y	3
		The facilitator reinforces that there is not a good or bad choice	Y	Y	N	2
		Using non-judgemental door openers e.g. 'what do you find the hardest part of managing your condition'	N	N	N	0
		The facilitator encourages participants to draw from their own knowledge and experience to make their own decisions	Y	N	Y	2
Non-verbal body language	Facilitator uses non-verbal body language to convey interest and empathy	The facilitator maintains eye contact at a comfortable level	Y	Y	Y	3
		The facilitator has an open stance, facing the group with relaxed posture	Y	Y	Y	3
		The facilitator uses nodding of the head and facial expressions appropriately	Y	Y	Y	3
Active Listening	Facilitator uses active listening skills to convey that they have heard what the participant has to say	Clarification – 'could you tell me a little more about that'	Y	N	N	1
		Paraphrasing – 'If I'm hearing you correctly…,' "Are you saying that…'	Y	N	N	1
		Reflection – 'it sounds like…', 'I get the impression that……	N	N	N	0
Total (/10)			8	5	5	

Fidelity Assessment Tool – Control Part II

Assessor/Coder	Workshop ID
SM	1 – Red 2 – Orange 3 – Pink

Review Key

The tools below have been used whilst viewing the recording of the education session to observe the use of facilitator behaviours.

N	Not Observed	These behaviours were **NOT OBSERVED**
Y	Observed	These behaviours were **OBSERVED**

Key Content	Y/N			
	Con 1	Con 2	Con 3	Total
Review of physical activity recommendations for people living with type 1 diabetes	Y	Y	Y	3
Progressing physical activity - FIT	Y	Y	Y	3
Hypoglycaemia treatment	Y	Y	Y	3
Resources and onward referral	Y	Y	Y	3
Total (/4)	4	4	4	

Communication Skills

	Desired Behaviour	Supporting Behaviours Observed	Y/N			
			Con 1	Con 2	Con 3	Total
Non-judgemental	Facilitator avoids judging participant choices and beliefs	The facilitator uses phrases such as 'it's your choice', 'it's your decision'	Y	Y	Y	3
		The facilitator reinforces that there is not a good or bad choice	Y	Y	Y	3
		Using non-judgemental door openers e.g. 'what do you find the hardest part of managing your condition'	N	N	N	0
		The facilitator encourages participants to draw from their own knowledge and experience to make their own decisions	Y	Y	Y	3
Non-verbal body language	Facilitator uses non-verbal body language to convey interest and empathy	The facilitator maintains eye contact at a comfortable level	Y	Y	Y	3
		The facilitator has an open stance, facing the group with relaxed posture	Y	Y	Y	3
		The facilitator uses nodding of the head and facial expressions appropriately	Y	Y	Y	3
Active Listening	Facilitator uses active listening skills to convey that they have heard what the participant has to say	Clarification – 'could you tell me a little more about that'	N	N	N	0
		Paraphrasing – 'If I'm hearing you correctly...,' "Are you saying that..."	Y	N	Y	2
		Reflection – 'it sounds like...', 'I get the impression that.....'	Y	N	Y	2
Total (/10)			8	6	8	

4.2.1   Data Analysis

Further to the detail provided in the data analysis section presented in Section 4.2, a third researcher was involved in the final stages of content analysis. Once M.B and G.L complied the data into categories, the third researcher (J.B) (not involved in the earlier steps of content analysis) reviewed the qualitative data to ensure consistency and integrity of analysis.

4.2.2   Recommendations for Future Research

Participants' concerns regarding the questionnaire may offer important insights for future questionnaire design. Although the discussion of Section 4.2 outlines why the current study focused on self-efficacy rather than knowledge acquisition, change to knowledge may be useful in future questionnaire design. It is possible that participants may have reported high self-efficacy, but experienced low knowledge and skills required to manage T1D and physical activity (Cordova et al., 2014). Closer examination of the relationship between self-efficacy, knowledge, and skill of participants may demonstrate improvements that were not captured in the questionnaire presented in Appendix C (Cordova et al., 2014).

4.3   Harms and Ethical Issues

For the purposes of this study, an adverse event was defined as "an untoward occurrence during the trial, which may or may not be causally related to the intervention or other aspects of trial participation" (Chan et al., 2013, p. 26). Increased rates of self-reported hypoglycaemia and or an increase in diabetes distress after participating in the pilot trial were considered potential areas of harm. We recorded self-reported hypoglycaemia and severe hypoglycaemia, as well as diabetes distress at t_1, t_2, and t_3. Participants were also encouraged to contact the research team or the Curtin Human Research Ethics Committee if they experienced any concerns.

No harms were reported throughout the study. Given physical activity can increase the risk of hypoglycaemia in those living with T1D (Michael C. Riddell et al., 2017), self-reported episodes of hypoglycaemia and severe hypoglycaemia related to physical activity were recorded to ensure hypoglycaemia events did not increase during the course of the study. Self-reported episodes of hypoglycaemia and episodes of severe hypoglycaemia did not rise throughout the study and did not differ between study arms (Table 4.1 and Table 4.2). Control participants were offered the intervention once all quantitative and

qualitative data collection was complete, and allocation had been revealed. Nineteen control participants expressed an interest in attending an intervention and nine attended.

Table 4.1

Standardised Effect Size and 95% Highest Density Interval of Self-Reported Hypoglycaemia

Self-reported episodes of hypoglycaemia	Effect size, d	95% HDI	
$t_1 - t_2$ hypo events	-0.07	-0.6, 0.44	
$t_1 - t_2$ hypo events (12 hrs‡)	-0.15	-0.73, 0.39	
$t_2 - t_3$ hypo events	-0.08	-0.64, 0.46	
$t_2 - t_3$ hypo events (12 hrs‡)	0.02	-0.51, 0.55	
$t_1 - t_3$ hypo events	-0.23	-0.79, 0.31	
$t_1 - t_3$ hypo events (12 hrs‡)	0.2	-0.25, 0.68	
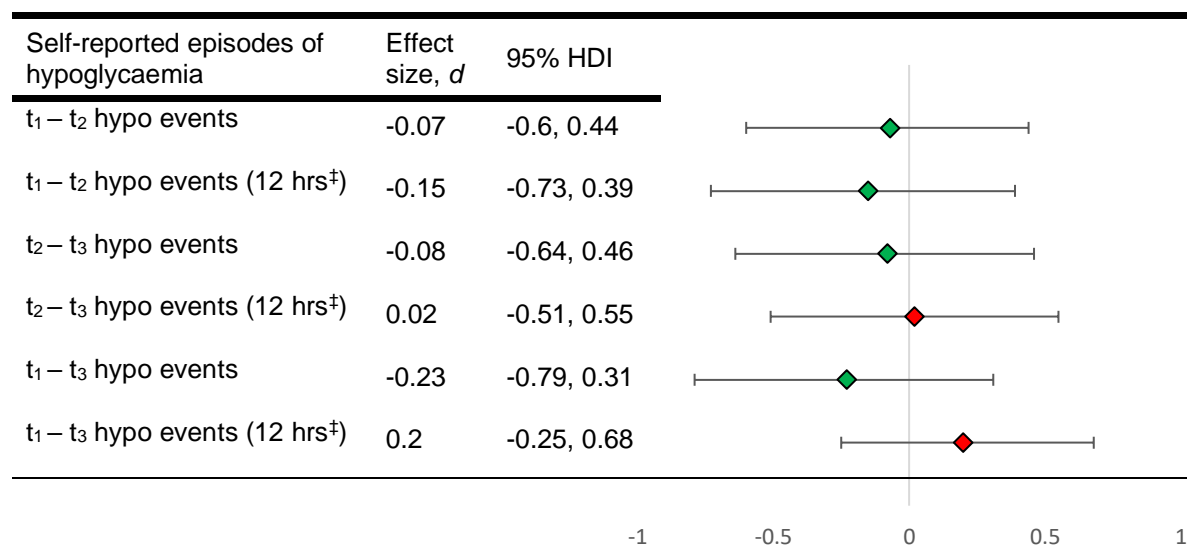
Note. HDI – highest density interval; hypo – hypoglycaemia; t_1 –Initial workshops, t_2 – Booster workshops, t_3 – 8 weeks after t_2

Green – favours the intervention; Red – favours the control

‡Reported events within 12 hours of being physically active

Table 4.2

Percentage of Participants Who Reported an Episode of Severe Hypoglycaemia

Study arm	t_1	t_2	t_3
Intervention	13%	3%	0%
Control	23%	2%	2%

Note. t_1 –Reported at least one episode of severe hypoglycaemia in the 12 months prior to the initial workshops, t_2 – Reported at least one episode of severe hypoglycaemia since t_1, t_3 – Reported at least one episode of severe hypoglycaemia since t_2

4.4   Summary

Pragmatic quantitative assessment of a single-blinded, pilot RCT indicated this to be an acceptable and feasible research design. Initial quantitative evaluation of Type 1 TACTICS for Exercise[©] indicated the intervention was feasible to administer, was acceptable to research participants, and preliminary findings indicated it was effective in reducing overall barriers to physical activity and diabetes distress, and improving self-efficacy and well-being. Qualitative assessment found most aspects of the study procedures were accepted and group education was acceptable and the preferred method of education on this topic. The final phase of the mixed method sequential design is integration of quantitative and qualitative results (Figure 3.1). Chapter 5 presents a joint display of the integrated findings and provides a discussion of how the qualitative data confirmed, explained/expanded, or was discordant with the quantitative findings.

Chapter 5   Discussion and Integration

The aim of this pragmatic, mixed methods study was to evaluate the feasibility, acceptability, and preliminary efficacy of Type 1 TACTICS for Exercise[©]; the first educational program of its kind. The program was designed to reduce FoH as a barrier to physical activity in adults living with T1D using a group, self-management approach. The study was undertaken using a two phase, explanatory sequential mixed methods design. Quantitative and qualitative enquiry occurred in two distinct phases, with data integration at the design, methods, and interpretation and reporting stage. The first quantitative phase (Section 4.1) revealed that Type 1 TACTICS for Exercise[©] was feasible and acceptable to participants, while preliminary findings indicated small-to-moderate effect sizes in favour of Type 1 TACTICS for Exercise[©] after 12-weeks, in relation to overall barriers to physical activity, self-efficacy, diabetes distress, and well-being (Brennan, Albrecht, et al., 2021). Process evaluation, which included the second qualitative phase and exploration of broader aspects of acceptability (Section 4.2), showed that the blinded RCT study design was widely accepted and group education was both acceptable and the preferred method of education in T1D management for physical activity (Brennan, Brown, Leslie, et al., 2021). This final chapter focuses on the integrated, meta-inferences of quantitative and qualitative results, presented using a joint display (Figure 5.1 and Table 5.1) which introduces areas of *confirmation*, *expansion/explanation*, and *discordance* between the data sets. Meta-inferences will be discussed in relation to the wider literature and how they address the gaps identified by Brennan, Brown, Ntoumanis, et al. (2021), in the systematic scoping review (Section 2.2). This chapter concludes with a discussion of dissemination, impact, and recommendations for future research.

5.1   Joint Display

The joint display figure and table (Figure 5.1 and Table 5.1) highlight the main findings of the systematic scoping review and how these findings informed the objectives of the mixed methods study. A summary of key quantitative and qualitative findings is then displayed against the corresponding study objectives. The purple hexagon (Figure 5.1) and the final table column (Table 5.1) integrate quantitative and qualitative results and display meta-inferences which address the mixed method study objectives. The *fit* of data integration is indicated by coloured text; green represents *confirmation*, orange represents *expansion/explanation*, and red represents *discordance* between the two datasets. Most of the meta-inferences fall within the *expansion/explanation* category which is consistent

with the purpose of the explanatory sequential mixed methods design (Creswell & Plano Clark, 2018). *Confirmation* was the next most frequent *fit* where both datasets arrived at similar conclusions, providing greater credibility (Fetters et al., 2013). Only one area of *discordance* was identified; possible explanations of the conflicting results will be discussed in this chapter. A narrative discussion in Section 5.2 will outline how the highlighted meta-inferences addressed gaps identified in the systematic scoping review (Section 2.2) (Brennan, Brown, Ntoumanis, et al., 2021). Figure 5.1 is presented first and provides a one-page abridged version of the joint display table (Table 5.1) to summarise key results and meta-inferences. For a more detailed summation of quantitative, qualitative, and meta-inferences, refer to Table 5.1.

Figure 5.1

Summarised Joint Display and Meta-Inferences of Scoping Review Findings and Quantitative and Qualitative Results
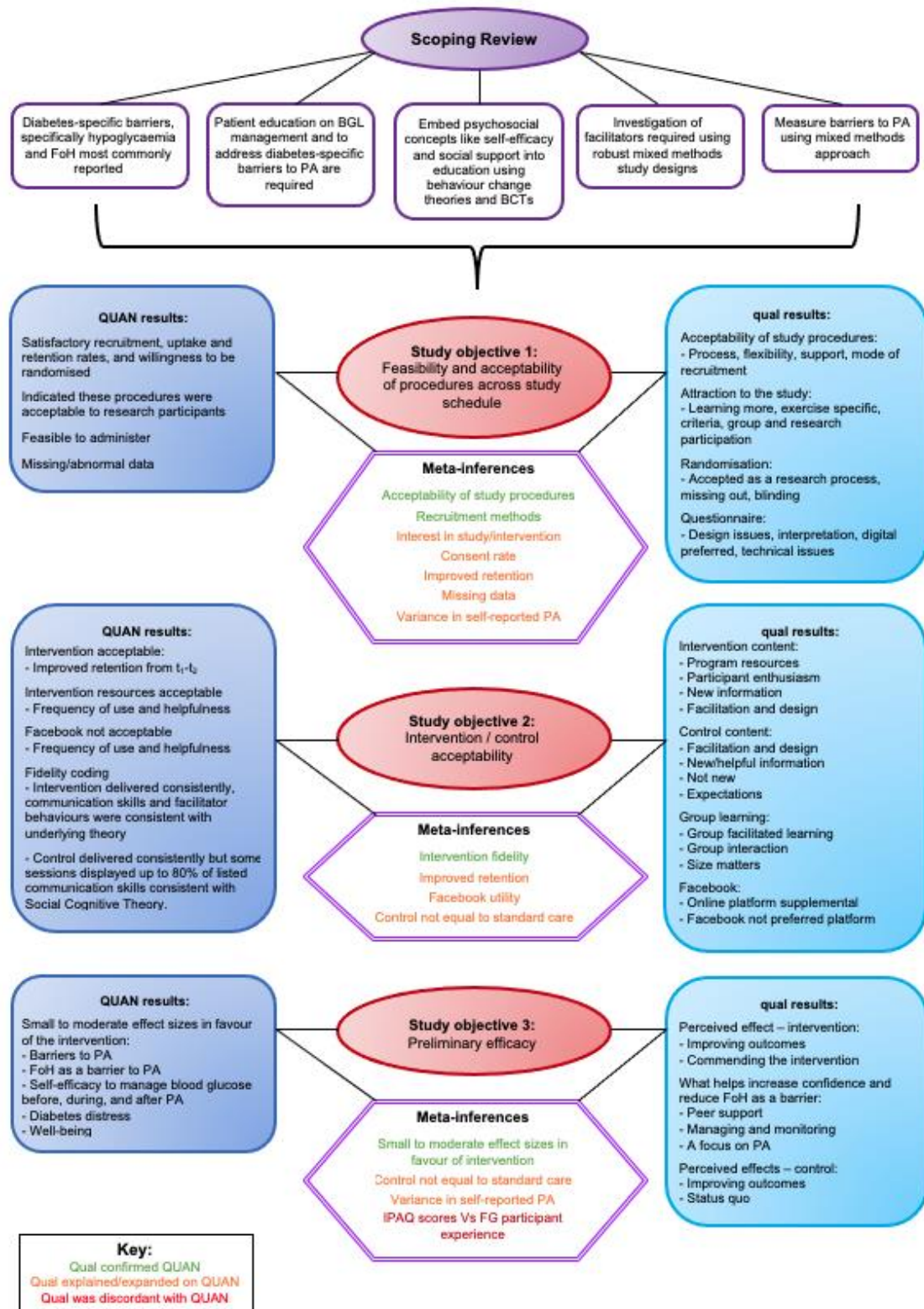
Note. FoH – fear of hypoglycaemia; BGL – blood glucose level; PA – physical activity; BCT – behaviour change technique; QUAN – quantitative; qual – qualitative; IPAQ – International Physical Activity Questionnaire-Short form; FG – focus group; t_1 – Initial workshops; t_2 – Booster workshops (4 weeks after initial).

A full joint display table is provided in Table 5.1. It provides a detailed tabular display of the evolution of the study objectives from the scoping review findings and how quantitative, qualitative, and meta-inferences respond to these objectives. The subsequent discussion in Section 5.2 refers to both the full joint display (Table 5.1) and the summary figure (Figure 5.1) to position the meta-inferences among the wider literature.

Table 5.1

Joint Display and Meta-Inferences of Scoping Review Findings and Quantitative and Qualitative Results

Scoping review findings (informing study objectives)	Study objective	QUAN results	qual results	Mixed methods meta-inferences (confirmation, expansion/explanation, discordance)
Very few trialled facilitators of PA use robust study designs

Fully powered randomised controlled trials are required to establish efficacy of behaviour change interventions targeting hypoglycaemia/FoH and other psychosocial factors

Researchers are called to complement quantitative findings with qualitative assessment of acceptability | Feasibility and acceptability of procedures across study schedule | Satisfactory recruitment rates, uptake and retention rates, and willingness to be randomised indicated the study procedures were acceptable to research participants

Feasible to administer with a modest research budget – completed within pre-determined timeframes

173 participants assessed for eligibility

149 (86%) eligible

117 (79%) consented to randomisation

Dropout rate 26% between t_0 and t_1 | Acceptability of overall study procedures:
- Process
- Flexibility
- Support
- Mode of recruitment

Attraction to the study:
- Learning more
- Exercise specific
- Criteria
- Group participation
- Research participation

Randomisation:
- Accepted as a research process
- Missing out | **Confirmation:**
QUAN assessment of acceptability of study procedures including achieving the target sample size and satisfactory sample at t_1 was **confirmed** by qual data – few issues with registration, screening, consent, attendance.

QUAN results showed Diabetes WA® mass email distribution as the most successful recruitment method **confirmed** with qual data relating to mode of recruitment

Expansion:
QUAN data indicated, through recruitment rates, sound interest in the study/intervention. This was **expanded** upon through qual data explaining that participants were attracted to the study because the program was specific to exercise, was group-based, and they wanted to learn more.

The 79% consent rate was partially **explained** by qual data suggesting although randomisation was not a deterrent for most and was accepted, some participants |

Scoping review findings (informing study objectives)	Study objective	QUAN results	qual results	Mixed methods meta-inferences (confirmation, expansion/explanation, discordance)
		Retention 81% between t_1 and t_2 Questionnaire completion 97% between t_1 and t_2 and 95% between t_2 and t_3 Missing/abnormal data: - Self-efficacy scale (managing BGLs for PA)	- Blinding Questionnaire: - Design issues - Interpretation - Digital preferred - Technical issues	**explained** that it gave them a sense of missing out or being told the wrong information. Retention improved from t_1 to t_2 (compared to t_0 to t_1) which was partially **explained** by qual data citing participants' positive experience with group education, feeling less judged, feeling supported by the group, and preferred this setting to one-on-one. Missing/abnormal data were **explained** by qual data which revealed a small number of participants reporting technical issues with questionnaires. Large variance in self-reported PA may have been **explained** in part by some participants using objective means to answer the PA questions, while others relied on recall.
Diabetes-specific barriers (specifically, hypoglycaemia/FoH) are the most reported barriers to PA among adults living with T1D Disparity between what is known about barriers to PA and what is done to facilitate PA	Intervention / control acceptability	Intervention acceptability: Although the intervention arm experienced greater initial attrition than the control (33% versus 20%), retention improved (from 67% to 85%) in the intervention arm from t_1-t_2 Intervention resource utility:	Intervention content: - Program resources - Participant enthusiasm - New information - Facilitation and design	**Confirmation:** Intervention fidelity outcomes were **confirmed** by qual data indicating participants preferred the group setting, felt supported, and learnt from others in the group. **Expansion:** Participant enthusiasm and favourable comments relating to group education, intervention resources, and content **expands** on QUAN results showing improved retention

Scoping review findings (informing study objectives)	Study objective	QUAN results	qual results	Mixed methods meta-inferences (confirmation, expansion/explanation, discordance)
Patient education on blood glucose management for PA should be offered

Behaviour change theories that propose psychosocial concepts like self-efficacy need to be embedded within diabetes education to facilitate PA behaviour change

Few studies reported BCTs

Trials should include interventions based on sound theoretical foundations, using and reporting appropriate BCTs.

Feature social support in interventions to address barriers to PA

Researchers are called to complement quantitative findings with qualitative assessment of acceptability | | 8 weeks post intervention-initial:
68% used take home resource
64% found it helpful
61% used it 2-5 times

12 weeks post intervention-initial:
36% used take home resource
65% found it helpful
70% used it 2-5 times

Facebook utility:
8 weeks post intervention-initial:
45% used Facebook group
41% found it helpful
56% used it 2-5 times

12 weeks post intervention-initial:
33% used Facebook group
45% found it helpful
42% used it 2-5 times

Intervention fidelity:
Content, communication skills, and facilitator | Control content:
- Facilitation and design
- New/helpful information
- Not new
- Expectations

Group learning:
- Group facilitated learning
- Group interaction
- Size matters

Facebook:
- Online platform supplemental
- Facebook not preferred platform | in the intervention arm once participants had attended their initial workshop.

qual data showed participants' ambivalence towards the private Facebook group and **explained** this was not their preferred platform. This qual data **explains** why less than half used the Facebook group and those who did, mostly found it 'somewhat helpful', as opposed to 'helpful', and used it modestly. One participant **expanded** on this further by suggesting the Facebook group would get better once it grows.

qual data indicated control content was new and helpful to participants, who were encouraged by the language used, while some experienced improved outcomes. This **expands** on QUAN results which:
  Hypothesised that the 'standard care' arm received over and above what the average person with T1D is generally exposed to and, as such, theorised that the relative effects of the intervention may have been diminished

  Showed some sessions were assessed as displaying up to 80% of listed communication skills consistent with SCT |

Scoping review findings (informing study objectives)	Study objective	QUAN results	qual results	Mixed methods meta-inferences (confirmation, expansion/explanation, discordance)
		behaviours were consistent between intervention groups and consistent with underlying theory Control fidelity: Consistent delivery of content between control groups Some control sessions were assessed as displaying up to 80% of the listed communication skills consistent with SCT		
Provide balanced and insightful representation of the barriers faced by the T1D population using a mixed method approach; this might include using a validated quantitative tool such as the BAPAD1, together with qualitative focus group interviews Very few trialled interventions to address FoH as a barrier to PA	Preliminary efficacy	Small-moderate effects in favour of the intervention: t_1 versus t_2: FoH as a barrier to PA ES=-0.33 [-1.1, 0.42], ROPE%=30.49% Barriers to PA ES=-0.34 [-0.88, 0.19], ROPE%=28.6% Self-efficacy managing BGL after PA	Perceived effect – intervention: - Improving outcomes - Commending the intervention What helps to increase confidence and reduce FoH as a barrier: - Peer support	**Confirmation:** Small to moderate effects in favour of the intervention were **confirmed** by qual data relating to positive intervention outcomes (mental health, FoH and hyperglycaemia as barriers to PA, and confidence). Most outcomes showed effect sizes in favour of the intervention (rather than the control) which is consistent with the qual category, 'status quo'. **Expansion:**

Scoping review findings (informing study objectives)	Study objective	QUAN results	qual results	Mixed methods meta-inferences (confirmation, expansion/explanation, discordance)
Behaviour change theories that propose psychosocial concepts like self-efficacy need to be embedded within diabetes education to facilitate PA behaviour change Psychosocial factors need to be addressed		ES=0.46 [0.01, 0.9], ROPE%=12.8% Well-being ES=0.32 [-0.13, 0.76], ROPE%=28.8% **t_2 versus t_3:** FoH as a barrier to PA ES=-0.31 [-0.77, 0.14], ROPE%=30.6% Barriers to PA ES=-0.36 [-0.89, 0.18], ROPE%=25.5% Diabetes distress ES=-0.38 [-0.89, 0.12], ROPE%=22.9% **t_1 versus t_3:** Barriers to PA ES=-0.38 [-0.92, 0.17], ROPE%=24.7% Self-efficacy managing BGL (<10 treated as missing): Before PA	- Managing and monitoring - A focus on PA Perceived effects – control: - Improving outcomes - Status quo	QUAN results lead to a hypothesis that the 'standard care' arm received over and above what the average person with T1D is generally exposed to and, as such, the authors theorised that the relative effects of the intervention may have been diminished. qual data **expanded** on this with control participants suggesting content was new and helpful, they were encouraged by the language used, and some experienced improved outcomes. Large variance in self-reported PA may have been **explained** in part by qual data which outlined that some participants used objective means to answer the PA questions, while others relied on recall. **Discordance:** IPAQ-SF scores and corresponding standardised mean difference are **discordant** with qual data which indicated some participants experienced improvement in physical activity participation.

Scoping review findings (informing study objectives)	Study objective	QUAN results	qual results	Mixed methods meta-inferences (confirmation, expansion/explanation, discordance)
		ES=0.32 [-0.15, 0.77], ROPE%=29.4%		
		During PA ES=0.31 [-0.14, 0.76], ROPE%=30.4%		
		After PA ES=0.45 [0, 0.91], ROPE%=13.1%.		
		Well-being ES=0.36 [-0.12, 0.8], ROPE%=24.07%		

Note. PA – physical activity; QUAN – quantitative; qual – qualitative; FoH – fear of hypoglycaemia; BGL – blood glucose level; BCT – behaviour change technique; T1D – type 1 diabetes;

BAPAD1 – Barriers to Physical Activity-type 1 scale; ES – effect size; ROPE – region of practical equivalence; IPAQ-SF – International Physical Activity Questionnaire-Short form; SCT – Social

Cognitive Theory; t_1 –Initial workshops; t_2 – Booster workshops (4 weeks after initial); t_3 – 8 weeks after t_2

Green – confirmation; Orange – expansion; Red – discordance

5.2 Discussion of Meta-Inferences

5.2.1 Study Procedures

The systematic scoping review called for fully powered RCTs to establish efficacy in behaviour change interventions targeting the most pertinent barriers to physical activity in people living with T1D (Brennan, Brown, Ntoumanis, et al., 2021). Before investigating the effectiveness of Type 1 TACTICS for Exercise[©] in a definitive trial, the first objective was to assess feasibility and acceptability of study procedures used across the pilot trial (Eldridge et al., 2016; Sekhon et al., 2017). Qualitative findings *expand* and *confirm* quantitative results asserting that procedures used across the study schedule were acceptable to most participants and feasible to administer (Figure 5.1 and Table 5.1). Given very few studies have trialled facilitators of physical activity using robust study designs (Brennan, Brown, Ntoumanis, et al., 2021), this is an important finding that enables implementation of future robust study designs to confirm effectiveness.

Although barriers to trial participation have been well documented in other populations (Ross et al., 1999), barriers specific to people living with T1D were only recently reported and were specific to those newly diagnosed with T1D (Henshall et al., 2018). Therefore, the use of robust mixed methods to fully understand recruitment, retention, and dropout rates in the Type 1 TACTICS for Exercise[©] pilot trial provided crucial insights into acceptable study methods for future trials in this population. These methods suggested that adults living with T1D are interested in participating in RCTs of group self-management behaviour change interventions (including returning for a booster session), are willing to be randomised, and provide questionnaire data across a period of at least three months. Recruitment of people with T1D to trials is difficult and has been as low as 17% in a trial of group education for this population (DAFNE Study Group, 2002). However, data integration show recruitment rates and methods in the Type 1 TACTICS for Exercise[©] pilot trial were acceptable. This was evidenced by quantitative recruitment rates and qualitative data explaining participants were attracted to the study because the program was specific to exercise, was group-based, and because they wanted to learn more (Figure 5.1 and Table 5.1). These meta-inferences resonate with the systematic scoping review findings, that interventions to facilitate physical activity are both required and desired by people living with T1D, and that it is possible to overcome diabetes-specific barriers to participation (Brennan, Brown, Ntoumanis, et al., 2021).

Although randomisation was accepted by most as a research process and despite control participants being offered the intervention at the conclusion of the study, qualitative data

suggested that randomisation gave some participants a sense of missing out or being told the wrong information (Brennan, Brown, Leslie, et al., 2021). This insight may *explain* why some eligible individuals did not give their consent (consent rate = 79%) and why others dropped out (control dropout = 20%) (Brennan, Albrecht, et al., 2021) (Figure 5.1 and Table 5.1). Acceptability of randomisation procedures is a common area of concern in RCT designs (Featherston & Donovan, 1998; Kerr et al., 2004). All existing RCTs investigating facilitators of physical activity in people living with T1D are reported as pilot studies (Brazeau et al., 2014; Hasler et al., 2000; Narendran et al., 2017), but only one (Narendran et al., 2017) openly discussed aspects of feasibility and acceptability. As far as it has been possible to ascertain from the literature, this research group were also the only other authors to use qualitative methods to investigate acceptability of their RCT procedures (Henshall et al., 2018). While focused on a 'newly diagnosed' cohort, there were some parallels in overall conclusions regarding randomisation, namely that a clearer explanation of equipoise is required (Henshall et al., 2018). Future trials should ensure participant information is reviewed to effectively reassure participants that they will not miss out on an effective intervention nor receive incorrect or misleading information, regardless of their allocation. Individuals may also benefit from an opportunity to discuss randomisation with research personnel prior to consent (Featherston & Donovan, 1998).

5.2.2   Intervention and Control Acceptability

Understanding indicators of acceptability of study procedures (for example, intervention dropout and retention rates) may elucidate intervention acceptability, the second objective of the pilot trial. Improved retention seen after t_1 in the intervention arm is explained by participant enthusiasm towards the intervention found in the qualitative data and is indicative that the face-to-face aspect of the intervention was acceptable to participants (Figure 5.1 and Table 5.1). Although structured diabetes self-management education is necessary, it is not sufficient to sustain improvements in outcomes beyond 6 months (Funnell et al., 2005; Pillay et al., 2015); ongoing support is required to maintain skills, knowledge, and behaviour changes (Beck et al., 2017; Powers et al., 2015). To facilitate ongoing support, Type 1 TACTICS for Exercise© incorporated an intervention Facebook™ group but meta-inferences conclude that it may not have been an acceptable aspect of the intervention. Data integration explained that limited interaction and satisfaction with the private Facebook™ group was due to an overall ambivalence towards Facebook™ and was not participants' preferred platform. It is vital the participant selects an ongoing support resource or activity that best suits their individual needs (Beck et al., 2017). Asking participants for their preferred platform in advance and pursuing the most popular

preference may improve uptake and engagement. Regardless of the platform, ongoing support should aim to nurture psychosocial concepts including self-efficacy and social support to allow ongoing social learning and facilitate ongoing behaviour change as recommended by the systematic scoping review (Brennan, Brown, Ntoumanis, et al., 2021).

Intervention fidelity assessment showed content, communication skills, and facilitator behaviours were delivered reliably and were consistent with underlying Social Cognitive Theory (Brennan, Brown, Leslie, et al., 2021). This finding was *confirmed* by qualitative results where participants outlined a preference for group education, citing reasons consistent with Social Cognitive Theory (Bandura, 1977). It is the first time intervention fidelity has been measured and reported in an experimental trial related to physical activity behaviour change in the T1D population. These meta-inferences provide greater confidence in the overall conclusion that the intervention was delivered consistently and as proposed. Assessing fidelity promotes a greater understanding of the study findings, meaningful revision of the intervention, and study replication for future definitive trials (Carroll et al., 2007; Leichsenring et al., 2011; Moore et al., 2015; O'Donnell, 2008). High intervention fidelity has also been shown to improve participant outcomes (Carroll et al., 2007; Leichsenring et al., 2011; Moore et al., 2015; O'Donnell, 2008), which promotes stakeholder confidence in the program.

Fidelity coding of the control sessions revealed that some sessions were assessed as displaying up to 80% of the listed communication skills consistent with Social Cognitive Theory (Bandura, 1977), despite attempting to deliver the content using a didactic facilitation style (to minimise social learning and hence mimic standard care). These quantitative outcomes were *expanded* upon by qualitative findings indicating that control participants were encouraged by the language used throughout the program, perceived improved outcomes, and found the content new and helpful. These inferences support the notion that between-group differences may have been greater with a different control condition (Karlsson & Bergmark, 2015). Randomised controlled trials investigating the effect of interventions on physical activity participation in T1D participants have used passive control designs in the past (Brazeau et al., 2014; Hasler et al., 2000; Karlsson & Bergmark, 2015; Narendran et al., 2017), which may have been appropriate for those examining the effect of individual consults. (Hasler et al., 2000; Narendran et al., 2017). Brazeau et al. (2014) used leaflets as the control despite the comparison arm being a group intervention, making it unclear whether the reported effects were due to specific ingredients or counterfactual treatment effects (Karlsson & Bergmark, 2015). Meeting

other people with T1D in a group setting was novel and attractive to many of the focus group participants involved in the Type 1 TACTICS trial, and therefore it is proposed the group environment itself may derive some benefit (Brennan, Brown, Leslie, et al., 2021). Including a group control comparator is important and acceptable, however future definitive RCTs should ensure a different person, not trained in Social Cognitive Theory, deliver revised control content which more closely aligns with information available in standard care.

It is crucial to establish intervention acceptability in the evaluation of all healthcare interventions, particularly in the pilot phase (Moore et al., 2015; O'Cathain et al., 2019; Sekhon et al., 2017). This comprehensive mixed methods assessment of intervention acceptability has shown that theory-driven self-management group education to address complex diabetes-specific barriers to physical activity is acceptable to adults living with T1D, addressing an important gap identified in the systematic scoping review (Brennan, Brown, Ntoumanis, et al., 2021) (Figure 5.1 and Table 5.1). Although acceptability is not the only condition for intervention effectiveness, participants are more likely to adhere to treatment recommendations and benefit from improved clinical outcomes in an intervention that has been deemed acceptable (Sekhon et al., 2017).

5.2.3   Preliminary Efficacy

The final objective of this study was to examine the potential effects of the intervention on primary and secondary outcomes (Table 3.1). Overall preliminary efficacy has been *confirmed* by meta-inferences showing congruence between quantitative results (small to moderate effects in favour of the intervention) and positive intervention outcomes outlined by qualitative data. This mixed method approach addresses the recommendations of the systematic scoping review by providing a balanced and insightful representation of barriers to physical activity, a primary outcome of the pilot RCT (Table 5.1). Indications from quantitative (fidelity coding and effect size estimates) and qualitative data suggest the active control may have been of some benefit, thus strengthening the observed effect size estimates in favour of the intervention. Although most participants experienced positive effects, some control focus group participants experienced status quo, meaning they reported little change to primary and secondary outcomes. The status quo category fits with the overall hypothesis that the intervention would show greater effects on primary and secondary outcomes when compared to the control and was *confirmed* by small to moderate effects in favour of the intervention. These insights are promising and are the first step towards a fully powered definitive trial to determine the effect of a theory driven behaviour change intervention encompassing psychosocial concepts like self-efficacy to

facilitate physical activity participation (Brennan, Brown, Ntoumanis, et al., 2021). Further investigation with a more representative control design, in a definitive trial is now warranted.

Change to physical activity was measured using the IPAQ-SF (Craig et al., 2003) for reasons described in Section 3.5.4. Large variance was observed in self-reported physical activity levels which may be *explained* by qualitative data which clarified that some participants referred to their own physical activity tracking devices to answer the IPAQ-SF while others relied on recall only. Large variance also explains *discordance* surrounding IPAQ-SF data, which suggested very little overall improvement in physical activity levels, and qualitative data suggesting some participants did experience improvement in physical activity levels. In the wider literature, only one identified experimental study appeared to investigate the effect of an intervention on physical activity using a mixed methods approach (Henshall et al., 2018; Narendran et al., 2017). This study used accelerometer data, self-reported exercise diaries, and qualitative enquiry to assess change to physical activity. Although the topic guide listed questions surrounding change in physical activity, these specific responses were not reported or integrated with quantitative data in the article (Henshall et al., 2018). The use of gold standard accelerometry may mitigate the need for qualitative investigation of perceived effects, however qualitative enquiry may still provide valuable data on participant experience, as demonstrated by Henshall et al. (2018). Should physical activity become a primary outcome in future definitive trials, device-driven measures of physical activity are recommended to improve the reliability and validity of this outcome, while qualitative methods could provide essential insights to explain contextual factors associated with variation in outcomes (Moore et al., 2015).

5.3   Study Strengths and Limitations

The strength of this study lies in the robust mixed methods study design to advance understanding in an overlooked area of research. Integration of rigorous quantitative and qualitative methods resulted in a comprehensive and pragmatic understanding of the feasibility, acceptability, and preliminary efficacy of Type 1 TACTICS for Exercise[©]. The intervention and study methods were further strengthened by engaging a steering group from the planning phase through to dissemination (Section 3.3). Stakeholders included T1D consumers, credentialled diabetes educators, an endocrinologist, a clinical psychologist, and a representative from Diabetes WA[®] and the National Diabetes Services Scheme (NDSS). Involving key stakeholders from the beginning contributed to developing a study design and intervention that was feasible and acceptable, and ensured meaningful

dissemination to all relevant stakeholders, increasing the likelihood of effective research translation. Strong partner organisations including Diabetes WA® and the Australian Diabetes Educator Association – Research Foundation validated the aims of the pilot RCT and intervention, and ensured they aligned with industry priorities. Future definitive trials are now possible and well positioned to provide valid and reliable investigations to establish efficacy and the utility of Type 1 TACTICS for Exercise© in reducing FoH and improving physical activity participation.

Conceptually, this study was the first to systematically identify and address important gaps in the literature pertaining to diabetes-specific barriers to physical activity and the lack of evidence-informed interventions to address them. Type 1 TACTICS for Exercise© was designed to address FoH as a barrier to physical activity and is the first of its kind to undergo rigorous mixed methods investigation. Study findings enhance the understanding of how to effectively address diabetes-specific barriers to physical activity and provides the foundations for a more active T1D population.

The application of Bayesian statistics was another strength of this study. Given the focus on feasibility and acceptability, the pilot RCT was not powered to detect statistically significant differences between groups; as such *p* values were not reported (Eldridge et al., 2016). The use of Bayesian estimation with regions of practical equivalence (ROPE) allowed the reader to consider the proximity of the parameter to the ROPE around the null value without having to accept or reject the null hypothesis (Kruschke, 2013). The use of Bayesian methods also satisfied study objectives examining preliminary efficacy and provided estimates for future trials.

Study limitations have been identified in publications presented in Chapter 4. Previously reported limitations that warrant further discussion, and limitations that are not otherwise described are reported here. Generalisability of the study findings may be limited. The pilot RCT sample comprised individuals who were of predominantly English or non-Indigenous Australian ancestry, and who were tertiary educated. Future studies should aim to determine if the study findings translate to other settings and cohorts that are culturally diverse and/or possess lower literacy.

Further limitations concerning generalisability of the study findings relate to the very active sample (median = 2305.5 [1,445-4,166] MET.min/wk), which does not accurately represent the wider T1D population (Australian Institute of Health Welfare, 2020; Speight et al., 2011). Although FoH was the strongest barrier to physical activity among other listed barriers, the average baseline score of item two on the BAPAD1 scale (FoH) was

3.9 ±1.94, corresponding to 'neutral' on the 7-point Likert scale (Brennan, Albrecht, et al., 2021) (Appendix B: Appendix 3). These baseline characteristics were substantial confounders in the overall findings of the pilot RCT. Future trials may need to consider screening and excluding participants based on their baseline physical activity level and their reported barriers to physical activity.

Unlike other trials (Narendran et al., 2020), this pilot did not exclude participants based on their choice of insulin delivery method or use of other technologies. The pilot sample did not allow exploration of how these confounders may have impacted on primary and secondary outcomes. Although diabetes technology has been shown to improve many aspects of self-management (Atkinson et al., 2014), it is still unclear what effects technology has on initiating physical activity participation, though it is plausible to speculate a positive association exists (Brennan, Brown, Ntoumanis, et al., 2021). Future trials should be powered to detect such effects and may consider the inclusion of continuous glucose monitoring/intermittently scanned continuous glucose monitoring as a baseline condition.

Although fidelity of facilitator behaviours and delivered content was assessed, the research budget did not allow for more than one coder. As such, it was not possible to measure reliability of the fidelity coding process. To ensure a more robust assessment of fidelity, future research should consider two or more coders. Behaviour change techniques were mapped against the intervention facilitator manual post hoc. Although post hoc mapping of the manual provided confirmation of BCTs within the manual, it does not verify to what extent these BCTs were demonstrated throughout the intervention, nor whether they were demonstrated consistently across all groups. Future trials should ensure both independent coders are trained and experienced in BCTs and include this in the intervention fidelity assessment, alongside facilitator behaviours.

Finally, the involvement of the PhD candidate across all stages of data collection and analysis may have introduced unavoidable bias. Quantitative and qualitative data may have been subject to social desirability bias given the researcher's presence at the point of collection (Althubaiti, 2016). Steps were taken to minimise potential bias of this nature by ensuring the PhD candidate remained in a different room to participants until questionnaires were completed and having another member of the research team facilitate focus group interviews. Close supervision of the PhD candidate from experienced members of the research team ensured potential bias was avoided as much as possible during recruitment, screening, randomisation, intervention/control delivery,

and data collection. Future research budgets should allow for adequate research support personnel to minimise this risk of bias.

5.4 Dissemination, Impact, and Future Research

Evidence of acceptability, feasibility, and preliminary efficacy of Type 1 TACTICS for Exercise© may provide a viable strategy to address principles three and four of the Australian National Diabetes Strategy – facilitation of person-centred care and self-management throughout their life and reducing health inequalities by way of access to essential education, respectively (Department of Health, 2015). Unfortunately, existing health promotion efforts geared towards the general population are not equipped to address the complex needs of those living with T1D. People living with T1D have not been afforded access to structured self-management programs which aim to address T1D-specific barriers to physical activity. Although the preliminary findings of the pilot RCT are not sufficient to categorically confirm Type 1 TACTICS for Exercise© will be effective in addressing these needs, it has generated substantial interest from partner organisations (Diabetes WA® and the NDSS) as an option to address this known deficit. Ideally, the roll-out of Type 1 TACTICS for Exercise© would be subsequent to a multi-centre definitive RCT that confirms the preliminary findings (Milat et al., 2016). Eager to fill the gap in services, partner organisations are interested in pursuing local program roll-out in parallel with future research efforts.

Dissemination of findings to key stakeholders, particularly the NDSS, may facilitate equitable and affordable access to Type 1 TACTICS for Exercise© for all Australians living with T1D. Early planning and engagement with a representative of the NDSS and Diabetes WA® via the project steering group (Section 3.3) ensured the program met government and local organisational requirements to be considered for future local and national funding rounds. To precipitate local implementation, the following have or will occur:

- Findings have been reported to Diabetes WA® executives, board, and staff including diabetes educators, administrative, and coordination teams.

- Type 1 TACTICS for Exercise© will be put through the NDSS self-assessment tool and presented to the NDSS National Evaluation Team for consideration as an approved "topic specific program".

Type 1 TACTICS for Exercise© has the potential to develop the skills of diabetes health professionals to provide holistic, safe education to this population. Type 1 diabetes can be a challenging condition to manage, not only for the person living with the condition but also for diabetes health professionals supporting this population in ongoing self-management (Stuij et al., 2017). The complexity of managing BGLs with physical activity, along with diabetes-specific barriers can be a daunting aspect of self-management education for diabetes educators and other health professionals (Stuij et al., 2017). These difficulties experienced by diabetes educators are likely to have a direct impact on care and education received by this population, highlighted in the systematic scoping review (Brennan, Brown, Ntoumanis, et al., 2021). Standardising care in this area is likely to offer local diabetes educators the opportunity to upskill and improve confidence and competency in offering much needed education in this space. Dissemination to diabetes health professionals has occurred by:

- Publicising quantitative and qualitative publications to relevant health professionals using existing Diabetes WA® media platforms,

- Presenting findings at local and national diabetes conferences, including the Australasian Diabetes Congress 2020 (see Publications and Presentations

And will continue by:

- Developing health professional training modules and quality assurance framework to enable credentialled diabetes educators to facilitate Type 1 TACTICS for Exercise© consistently around Australia.

People living with T1D in Australia do not currently have access to evidence-informed, structured self-management education programs designed to address diabetes-specific barriers. Type 1 TACTICS for Exercise© was found to be acceptable, feasible, and potentially effective and is poised to fill this gap in service delivery. In doing so, Type 1 TACTICS for Exercise© may contribute to Goal 3 of Australian National Diabetes Strategy – reduce the occurrence of diabetes-related complications and improve quality of life among people with diabetes – given what is known about the effects of physical activity on the health of people living with T1D (Bohn et al., 2015; Chimen et al., 2012; Moy et al., 1993; Tielemans et al., 2013; Wadén et al., 2008; Yardley et al., 2014). To ensure effective dissemination of the study results to people living with T1D, the following plan has been enacted:

- Partner organisations, Diabetes WA® and Curtin University, hosted a research dissemination evening targeting adults living with T1D in Perth, Western Australia (14th October 2020). Research findings were disseminated to a group of 73 face to face and 6 online attendees.

- Published study results have been disseminated to all research participants and those who expressed an interest in the study who asked to be notified when publications become available.

- Study results and future plans for Type 1 TACTICS for Exercise© have been communicated to the Western Australian T1D community via Diabetes WA® subscription e-communications (over 7000 recipients).

Further research is required to confirm the findings of this pilot trial and to further consolidate self-management education in this complex area of diabetes management. Maintaining existing connections with the British research group, EXercise in Type One Diabetes (EXTOD), may facilitate future international research collaborations. Future research priorities include:

- A larger, multi-centred definitive RCT to confirm preliminary effectiveness presented in this thesis. This trial should aim to:

  o Target a less physically active cohort who identify FoH as a strong barrier to activity,

  o Review exclusion criteria to exclude those diagnosed with impaired hypoglycaemia awareness,

  o Consider more culturally diverse cohorts and those with lower literacy,

  o Seek further consultation with inactive and/or culturally diverse T1D representatives with varying levels of literacy to inform future recruitment strategies,

  o Extend intervention delivery phase to improve group sizes,

  o Provide potential and enrolled participants with a clearer explanation of equipoise,

  o Offer a revised control intervention which better reflects "standard care" in Australia,

- o Determine the utility of Type 1 TACTICS for Exercise© in improving physical activity participation,

- o Use device-measured physical activity and hypoglycaemia outcomes,

- o Ensure adequate power to explore potential confounders including insulin delivery method and/or the use of continuous glucose monitoring/intermittently scanned continuous glucose monitoring,

- o Develop and evaluate a facilitator training program for Type 1 TACTICS for Exercise© and assess ongoing program fidelity.

- Exploration of T1D technology and its impact on physical activity participation,

- Robust RCTs of systematically designed, theory-driven behaviour change interventions targeting physical activity in adults living with T1D,

- Ongoing exploration of barriers to physical activity in this population using a mixed methods approach,

- Comparison of item 2 of the BAPAD1 with scores of general fear of hypoglycaemia scales to determine if they are related.

Outcomes from this research may also inform research in other populations. For example, those experiencing heart disease may experience similar fears relating to physical activity, post cardiac event (Ahlund et al., 2013; Bäck et al., 2013). Future applications may also include youth T1D populations, whose physical activity habits and attitudes are in a pivotal phase of development and who are at risk of developing lifelong deleterious beliefs and attitudes towards to physical activity.

Should a larger trial confirm effectiveness and key stakeholders are agreeable, the implementation science framework outlined by Milat et al. (2016) can be used to formally integrate findings into practice and policy. *Increasing the Scale of Population Health Interventions: A Guide* (Milat et al., 2016), recommends a scalability assessment to assess: effectiveness, potential reach and adoption, alignment with strategic context, and acceptability and feasibility as the first step. The second step is to develop a scaling up plan which describes: the rationale for scale-up, the intervention, a situational and stakeholder analysis, required personnel, a suitable scale-up approach, an evaluation and monitoring framework, and resources required. The third step of this framework is to prepare for scale-up. The priorities in this step are to: consult with stakeholders, develop

and implement governance structures, build a constituency, and mobile resources. The last step is to scale-up the intervention by: managing organisational change, coordinating governance, monitoring performance and efficiency, and ensuring sustainability (Milat et al., 2016; Milat et al., 2013). This systematic and coordinated implementation approach will increase the impact of Type 1 TACTICS for Exercise[©] and ensure it benefits more people, and advances and sustains program development (Milat et al., 2016).

5.5   Summary and Conclusion

For the first time, T1D-specific barriers and facilitators of physical activity have been systematically reviewed and presented (Brennan, Brown, Ntoumanis, et al., 2021), substantiating the need for T1D-specific interventions grounded in behaviour change theory to address inactivity in this population. A pragmatic, two-phase, explanatory sequential mixed methods study was used to evaluate the feasibility, acceptability, and preliminary efficacy of Type 1 TACTICS for Exercise[©] designed to reduce FoH as a barrier to physical activity in adults living with T1D. Type 1 TACTICS for Exercise[©] used Social Cognitive Theory (Bandura, 1977) and the Dual Process Model (Chaiken et al., 1996) to target self-efficacy, knowledge, and skill to influence diabetes self-management and physical activity behaviour change. Mixed methods meta-inferences conclude that Type 1 TACTICS for Exercise[©] and the study methods used to evaluate it were feasible and acceptable to research participants. Data integration confirmed preliminary positive intervention effects in favour of the intervention for well-being, diabetes distress, FoH as a barrier to physical activity, and self-efficacy outcomes. A definitive trial is now required to replicate these preliminary findings and to determine the utility of Type 1 TACTICS for Exercise[©] for improving physical activity participation.

For the first time in Australia, an acceptable, evidence informed, structured self-management education program designed to address diabetes-specific barriers is accessible to people living with T1D. Equitable access to physical activity support is likely to contribute to ongoing efforts to improve physical activity participation in this population, and potentially improve critical health outcomes.

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Appendix D   Thesis Appendices

D.1   Conference and Public Presentations

Brennan, M. C., Albrecht, M. A., Brown, J. A., Leslie, G. D., Ntoumanis, N. (2020, November). *Type 1 TACTICS for Exercise$^©$: Reducing fear of hypoglycaemia as a barrier to physical activity* [Online oral presentation]. Australasian Diabetes Congress, Gold Coast, Australia.

Abstract

Title: Type 1 TACTICS for Exercise$^©$: Reducing fear of hypoglycaemia as a barrier to physical activity.

Aim: Fear of hypoglycaemia (FoH) is the most commonly reported barrier to physical activity (PA) among adults living with type 1 diabetes (T1D) and contributes to high rates of inactivity in this population. In order to address this we evaluated a self-management, group education program: Type 1 TACTICS for Exercise$^©$. Preliminary efficacy of this intervention will be discussed.

Methods: Preliminary efficacy was assessed using a pilot, single blinded randomised controlled trial in adults, living with T1D in Perth, Western Australia. Participants were randomised (1:1) to control (standard care) or intervention (Type 1 TACTICS for Exercise$^©$) arm. The intervention consisted of a three-hour self-management group education workshop, social media support group, and a one-hour booster workshop four-weeks later. The control consisted of a one-hour general information session, followed by a one-hour review session after four-weeks. Preliminary efficacy outcomes: barriers to PA (including FoH), attitudes and intentions towards PA, self-reported PA, self-efficacy, diabetes distress, and well-being. Bayesian methods were used to provide estimates of the distribution of credible values for the effect sizes, group means and standard deviations, and their differences.

Results: We consented and randomised 117 participants, of whom 86 (74%) attended initial workshops, and 81% attended the booster workshop thereafter. Participants were on average 45 ±11.68 years of age, physically active, and living with T1D for over 20 ±14.27 years. Small-moderate effect sizes in favour of the intervention were observed at 12-weeks for overall barriers to PA (ES=-0.38 [HDI -0.92, 0.17]), self-efficacy (blood

glucose management after PA) (ES=0.45 [0, 0.91]), diabetes distress (ES=-0.29 [-0.77, 0.15]), and well-being (ES=0.36 [-0.12, 0.8]).

Conclusions: Preliminary effect sizes in favour of Type 1 TACTICS for Exercise suggest this intervention may have an effect on barriers to PA and other key diabetes-specific outcomes. A definitive trial is now required to confirm these effects.

Brennan, M. C., Albrecht, M. A., Brown, J. A., Leslie, G. D., Ntoumanis, N. (2020, November). *Type 1 TACTICS for Exercise$^{©}$: Results of a pilot randomised controlled trial.* [Online oral presentation]. Australasian Diabetes Congress, Gold Coast, Australia.

Abstract

Aim: Our project evaluated the feasibility, acceptability, and preliminary efficacy of a group education intervention designed to reduce fear of hypoglycaemia (FoH) as a barrier to physical activity (PA) in adults with type 1 diabetes (T1D).

Methods: A pilot, single blinded randomised controlled trial in adults aged between 18-65 years, living with T1D in Perth, Western Australia. Participants were randomised (1:1) to control (standard care) or intervention (self-management education) arm. Primary outcomes: Feasibility and acceptability of the study procedures; Change to barriers to PA – FoH. Secondary outcomes: Change to attitudes and intentions towards PA, self-reported participation in PA, self-efficacy, diabetes distress, and well-being. Bayesian methods were used to provide estimates of the distribution of credible values for effect sizes, group means and standard deviations, and their differences.

Results: We recruited 12 participants per month over seven months from 4,866 emails sent (2.8% of all emails or 6.6% of opened emails). We consented and randomised 117 participants: 86 (74%) completed baseline data and attended initial workshops; 81% attended the booster workshop thereafter. Participants predominantly identified as Australian or English, were 45 ±11.68 years of age, reported high levels of activity, and had been living with T1D for 20 ±14.27 years. Small to moderate effect sizes in favour of the intervention were observed at 12 weeks for overall barriers to PA (ES=-0.38 [HDI -0.92, 0.17]), self-efficacy (blood glucose management after PA) (ES=0.45 [0, 0.91]), diabetes distress (ES=-0.29 [-0.77, 0.15]), and well-being (ES=0.36 [-0.12, 0.8]).

Conclusions: A single blind RCT of a self-management group education intervention was acceptable to participants of this study and feasible to deliver. Preliminary findings indicate small to moderate effects in key outcomes and affirms critical intervention components for future PA behaviour change programs in the T1D population.

Brennan, M. C. (2020, October). *Type 1 and physical activity*. Diabetes WA, An Evening for Discussion: Type 1 Diabetes and Physical Activity, Perth, Australia.

Brennan, M. C., Brown, J. A., Leslie, G. D., Ntoumanis, N. (2020, March). *Group education to address fear of hypoglycaemia as a barrier to physical activity in adults living with type 1 diabetes: A progress report.* [Oral presentation]. Australian Diabetes Educator Association, WA Branch conference, Bunbury, Australia*.*

Abstract

Background: Physical activity (PA) is recommended for all people living with type 1 diabetes (T1D), however many are not meeting current recommendations. Contributing to these low rates of PA are T1D specific barriers including fear of hypoglycaemia (FoH). Group education exploring strategies to manage blood glucose levels surrounding PA may address this barrier.

Aim: To provide an update on a trial examining the feasibility, acceptability and preliminary efficacy of a group education program designed to address FoH as a barrier to PA in adults living with T1D.

Methods: A pilot randomised control study design. The intervention consisted of a three-hour self-management group education workshop, social media support group, and one-hour booster workshop four weeks later. The control consisted of a one-hour general information session, followed by a one-hour review information session after four weeks. Adults between 18-65 years, living with T1D in Perth and surrounding regions were recruited using convenience sampling then randomly allocated to control or intervention arms. Validated tools were used to gather data relating to trial feasibility and preliminary efficacy. A sub-sample of participants were invited to focus groups.

Results: Baseline data (T1) was collected prior to the initial workshops for 86 eligible participants. Following intention to treat analysis, 83 responses were collected prior to the booster workshops (T2). Data collection for T3 (eight weeks post booster) is ongoing. Although dropout from randomisation to T1 was high (26%), retention improved from T1 to T2 (84%). Twenty-one participants attended a focus group within their allocated study arm. Data analysis will commence once T3 data collection is finalised.

Conclusion: Recruitment, screening, randomisation, intervention and control delivery and data collection (T1 and T2) are now complete.

Brennan, M. C., Brown, J. A., Leslie, G. D., Ntoumanis, N. (2019, October). *Addressing fear of hypoglycaemia as a barrier to physical activity*. JDRF-PEAK/EXTOD Conference, Glasgow, United Kingdom.
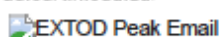
Invited presentation

EXTOD PEAK 18th & 19th October 2019 - Speaker registration form

Extod/PEAK Event Team <jen@peak-extod.events>
Sat 13/04/2019 1:01 AM
To: Marian Brennan <marian.brennan@postgrad.curtin.edu.au>

EXTOD Peak Email

Dear Brennan

On behalf of the organising committee of the JDRF EXTOD-PEAK conference I would like to take this opportunity to thank you for agreeing to present at this event. I am delighted to confirm your place as a speaker for the conference. You can find out further information about the conference and the latest details on the conference programme via the website hosted by the Association of British Clinical Diabetologists (ABCD).

The conference will take place at the Radisson Blu hotel in central Glasgow on the 18th and 19th October. The hotel is situated steps from Glasgow's Central train station, with bus links also located nearby. There is car parking near the hotel and the airport is 15 minutes by taxi.

Accommodation is available on the 17th & 18th October at the hotel, JDRF will also be hosting a private faculty dinner on the 17th & 18th October and you are cordially invited to attend.

Requires your action

In order to ensure we have the correct information for you and also to confirm the logistics I would be most grateful if you could complete the speaker registration form which includes details on your accommodation and dinner requirements, other logistical information and also your photograph and biography information for our speakers page on the website. If you have already submitted these details to us, you should be able to see these details and simply confirm they are accurate. Please complete the form as soon as possible to avoid receiving repeated automated reminders.

We will be in touch in due course with additional information about the conference and briefing details. In the meantime, if you have any questions please do not hesitate to contact us.

Yours sincerely,

Jen Atkinson
On behalf of the event organising team

Brennan, M. C. (2019, August). *The highs and lows of physical activity.* [Oral presentation]. 3-Minute Thesis Competition, Curtin University, Perth, Australia. **(Finalist)**

3MT Title: Addressing barriers to physical activity for people living with type 1 diabetes: Is group, self-management education the answer?

Thesis Title: Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.

Summary: Physical activity (PA) is routinely recommended to people living with Type 1 Diabetes (T1D). Despite its proven health benefits, people living with T1D are generally less active than the general population. This suggests 'T1D specific' barriers to PA exist. Current PA promotion initiatives do not consider the complexities of managing T1D and PA. Our project aims to see if a group education program can help people living with T1D, overcome T1D specific barriers to PA. A more active T1D population may reduce the incidence of diabetes related complications and improve the lives of people living with the condition.

Biography: Marian Brennan is a credentialed diabetes educator and accredited exercise physiologist at Diabetes WA in Perth, Western Australia. Marian completed her Master of Science in Diabetes in 2017 where she piloted a self-management, group education program to address barriers to physical activity in people living with type 1 diabetes. This exploratory work has informed Marian's current PhD research project. Marian was the recipient of the 2018 ADEA Diabetes Research Foundation, Research Fellowship.

3MT THREE MINUTE THESIS
FOUNDED BY THE UNIVERSITY OF QUEENSLAND

FINALIST 2019

Congratulations

Marian Clare Brennan

Professor Garry Allison
Associate Deputy-Vice Chancellor, Research Excellence

Curtin University

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Create change

Brennan, M. C. (2019, March). *Addressing barriers to physical activity for people living with type 1 diabetes: Is group, self-management education the answer?* [Oral presentation]. Mark Liveris Research Student Seminar, Perth, Australia.

Abstract

Addressing barriers to physical activity for people living with type 1 diabetes: Is group, self-management education the answer?

Presented by: Marian Brennan, School of Nursing, Midwifery and Paramedicine
Course: Doctor of Philosophy
Supervisor: Dr Janie Brown, School of Nursing, Midwifery and Paramedicine
Co-Supervisor: Professor Gavin Leslie, School of Nursing, Midwifery and Paramedicine
A/Supervisor: Professor Nikos Ntoumanis, School of Psychology

What do you do? We would like to find a way to help people living with type 1 diabetes (T1D), experience the same benefits and pleasures of physical activity (PA) as the general population. We believe group, self-management education could be where it begins.

Why do you do it? The benefits of PA are well documented. For people living with T1D, who already have a higher risk of vascular disease than the general population, PA is vital. The problem is, PA can create drastic fluctuations in blood glucose levels. Of greatest concern is hypoglycaemia (low blood glucose) which manifests with symptoms including dizziness, sweating, rapid heart rate, feeling faint, confusion, slurred speech, behaviour changes and if severe, can result in loss of consciousness, seizures and may require hospitalisation. These undesirable symptoms mean many people with T1D fear hypoglycaemia and report that this fear is the biggest barrier to PA.

What do you hope to find/have you found? We want to know if group, self-management education can help people living with T1D address fear of hypoglycaemia as a barrier, providing them the opportunity to get excited about PA. In addition, we hope to determine if group, self-management education can improve attitudes, intentions, and participation in PA, improve confidence to manage blood glucose levels for activity, improve well-being and reduce diabetes related distress.

What will that mean/imply? We are not aware of any evidence-based programs or services specifically designed to address fear of hypoglycaemia as a barrier to PA in this population. We hypothesise that by addressing the diabetes specific barrier of fear of

hypoglycaemia, people living with T1D may feel more confident and able to participate in wider community PA initiatives. A more active T1D population has potential to reduce long-term complications, improve quality of life and reduce annual healthcare costs.

D.2   Permission Statements

Permission: Wolters Kluwer

Subject: Re: Author permissions [ref:_00Dd0dixc._5003w1VJWDx:ref]
Date: Thursday, 3 June 2021 at 8:04:38 pm Australian Western Standard Time
From: "RLP - Journal Permissions"
To: Marian Brennan

Hello Marian,
After review approval is granted for you to use the final published article in your research thesis.

If you need any additional help please let us know

Regards
Tom

--------------- Original Message ---------------
From: Marian Brennan [marian.brennan@postgrad.curtin.edu.au]
Sent: 6/2/2021 9:32 PM
To: journalpermissions@lww.com
Subject: Re: Author permissions [ ]

Hi Tom,

Thank you for looking into this for me. The article in question is below:

Brennan M, Brown J, Ntoumanis N, Leslie G. Barriers and facilitators to physical activity participation in adults living with type 1 diabetes: A scoping review protocol. JBI Database System Rev Implement Rep. 2020;18(0):1-7. Doi:10.11124/JBISRIR-D-19-00219

Kind regards
Marian

Marian Brennan
MSc (Diabetes) **I** PhD Candidate
Accredited Exercise Physiologist **I** Credentialled Diabetes Educator
Curtin School of Nursing
Nursing | Midwifery | Paramedicine | Oral Health Therapy

Curtin University
Mobile | 0423 157 199

Twitter | @mariancbrennan

[Inline image name : image001.jpg]
CRICOS Provider Code 00301J (WA)

From: "RLP - Journal Permissions" <journalpermissions@lww.com>
Date: Thursday, 3 June 2021 at 1:06 am
To: Marian Brennan <marian.brennan@postgrad.curtin.edu.au>
Subject: RE: Author permissions [ ]

Hi Marian,
Thank you for your inquiry, it is Wolters Kluwer policy to only allow the final peer-reviewed article in a thesis. Would you be able to provide the article inforamtion in question and we can investigate further the possibility to allow it?

Regards
Tom.

Permission: Canadian Science Publishing

Subject:	FW: Permissions
Date:	Wednesday, 2 June 2021 at 10:40:01 pm Australian Western Standard Time
From:	CSP - Customer Support*
To:	Marian Brennan
Attachments:	image001.jpg, image002.png

Hello Marian

Thank you for your email. As mentioned below, as a not-for-profit scholarly publisher CSP provides authors with liberal rights regarding copyright. Authors can reuse and develop their own work without restriction. Authors may also reuse all or part of the article in other works created by them for non-commercial purposes, provided the published version is acknowledged through a note or citation.

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If a license for permission is required, a license can be obtained through Copyright Clearance Center's Republication Service.

Regards,

Zaineb Bouhlal
Customer Service and Sales Coordinator
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From: Marian Brennan <marian.brennan@postgrad.curtin.edu.au>
Sent: June 2, 2021 3:29 AM
To: CSP - Customer Support* <pubs@cdnsciencepub.com>
Subject: Permissions

Good morning,

RE: apnm-2020-0461
Barriers and facilitators of physical activity participation in adults living with type 1 diabetes: A systematic scoping review.

I note Canadian Science Publishing states, *"Authors may reuse all or part of the article in other works created by them for non-commercial purposes, provided the published version is acknowledged through a note or citation".* I am writing to confirm that as the lead author of the publication above, I may use the published article (in PDF form) in my research thesis for the award of Doctor of Philosophy at Curtin University.

Kindest regards
Marian

Marian Brennan
MSc (Diabetes) **I** PhD Candidate
Accredited Exercise Physiologist **I** Credentialled Diabetes Educator
Curtin School of Nursing

Permission: The Australian Diabetes Educator

Hi Marian,

I just spoke with Rachel and she said it is fine for you include the article in your PHD thesis.
Sorry it took so long to get back to you.

With best wishes, Kate

Dr Kate Marsh
PhD, MNutrDiet, BSc, Grad Cert Diab Edn & Mgt
AdvAPD, CDE, FADEA, FASLM
Editor, Australian Diabetes Educator (ADE)

From: Marian Brennan <marian.brennan@postgrad.curtin.edu.au>
Sent: Tuesday, 10 August 2021 2:59 PM
To: Editor@ADEA <editor@adea.com.au>
Subject: Permissions

Dear Kate,

I am following up the email below regarding permission to use a PDF version of our recently published
article in my PhD thesis.

Any assistance would be greatly appreciated.

Kind regards
Marian

Dear Kate,

RE: Brennan MC, Leslie GD, Ntoumanis N, Brown JA. Group self-management education to address fear of
hypoglycaemia as a barrier to physical activity: The role of behaviour change theories. Australian Diabetes
Educator. 2021;24(1).

I hope you are well.

I am writing to request permission to include the full version of the published article listed above in my
research thesis for the award of Doctor of Philosophy at Curtin University, for non-commercial purposes.
The thesis will be available on Curtin University's repository which is password protected.

Please let me know if you require further details to assist your decision.

Kind regards
Marian

Marian Brennan
MSc (Diabetes) I PhD Candidate
Accredited Exercise Physiologist I Credentialled Diabetes Educator
Curtin School of Nursing
Nursing | Midwifery | Paramedicine | Oral Health Therapy

Curtin University
Mobile | 0423 157 199

Twitter | @marianbrennan

Curtin University

Permission: Elsevier

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Permission guidelines

For further guidelines about obtaining permission, please review our Frequently Asked Questions below:

Can I include/use my article in my thesis/dissertation? —

Yes. Authors can include their articles in full or in part in a thesis or dissertation for non-commercial purposes.

D.3   Steering Group Terms of Reference

Curtin University

diabeteswa

TACTICS Steering Group

TERMS OF REFERENCE

Purpose and Aim

The **TACTICS** Steering Group (the Steering Group) has been established to provide a comprehensive stakeholder perspective on the research activity.

This aim is aligned with **delivering on the needs of all relevant stakeholders** and the National Health and Medical Research Council and Consumers Health Forum's *Statement on Consumer and Community Involvement in Health and Medical Research (2016)*.

Research Question

Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.

Terms of Reference

The Reference Group will provide or facilitate:

- Consumer, health professional and community perspectives on research activities across **The TACTICS Project**
- Advice and support on research grant applications and plain language summaries
- Links between consumers, health professionals, the community and researchers involved in **The TACTICS Project**
- Advice and expertise on consumer, health professional and community issues and priorities for research
- Advocacy on behalf of consumers, health professionals and the community where appropriate
- Input into the development of strategies to inform the wider community about research associated with the group

Membership

Membership of the Steering Group will be:

- **4** consumer members
- **4** researchers including senior staff representation
- **7** diabetes health professionals representing various settings in health care

The Steering Group will have the authority to co-opt other members as required or establish working parties for specific approved projects.

OPERATIONAL GUIDELINES

Term

Members will be appointed for a **3-4** year term

Meetings

The Steering Group will meet **approximately twice** a year with additional meetings as determined by the Group. The duration of Steering Group meetings will be no longer than **1.5** hours. The sitting members will determine the Steering Group meeting times on a majority rules basis. Steering Group members will also be required to pre-read meeting documents and if necessary and/or appropriate consult with other internal and external groups. Steering Group members may also be consulted on an ad-hoc basis between meetings if required.

1

Payment and Support

Consumer members (only) will be offered an honorarium, in line with WA Health Department and Health Consumers' Council WA guidelines, for each Steering Group meeting attended. This honorarium payment acknowledges any out-of-pocket expenses associated with attending the meetings.

All paperwork relating to the Steering Group meetings will be provided in an appropriate and timely manner at least one week prior to the Steering Group meeting. Steering Group members will be able to access support and mentoring for their position on the Steering Group from the Consumer and Community Health Research Network. Steering Group members will be offered training on consumer and community involvement in research. There will not be any cost to Steering Group members for participating in training.

Confidentiality

Steering Group members will have access to confidential information and documents about the research and as such, must agree to the following statements.

As a Steering Group member, I agree to:

- respect and understand the need for confidentiality
- take steps to ensure the appropriate disposal of confidential, draft or embargoed material
- not disclose the content of any project material including research results and findings prior to public release
- check with the team leader or Consumer and Community Health Research Network if I am unsure about confidentiality issues
- not share any anecdotal examples, particularly relating to consumer experiences, that may be discussed in meetings without the express permission of the team members

Reporting

The Steering Group will have input into reports on its role and activities and will be encouraged to report and promote these to their wider community groups.

Terms of Reference

The Steering Group Terms of Reference will be reviewed annually.

Accepted 2nd October 2018

Review date 2nd October 2019

2

D.4 Steering Group Consumer Members Confidentiality Agreement

Consumer and Community Health Research Network

Confidentiality Agreement

Community member will have access to confidential information and documents about the research and as such must agree to the following confidentiality statements.

I ………………………………………………………………… agree to:

- respect and understand the need for confidentiality
- take steps to ensure the appropriate disposal of confidential, draft or embargoed material
- not disclose the content of any project material including research results and findings prior to public release
- check with the team leader or Consumer and Community Health Research Network if I am unsure about confidentiality issues

Signed by community member: …………………………………………………………

Research teams may have access to confidential information about the consumers and community members they are working with and must agree to:

- not share any anecdotal examples, particularly relating to consumer experiences, that may be discussed in meetings without the express permission of the team members

Researcher Name:………………………………… Signed: ………………………………… Date:………………………

Consumer and Community Health Research Network staff member

Name:………………………………………………… Signature: ………………………………… Date:………………………

D.5 Diabetes WA® Permission

Curtin Human Research Ethics Committee
Curtin University
Kent Street
Bentley, Western Australia 6102

11ᵗʰ May, 2018

To whom it may concern,

It is my understanding that Marian Brennan will be conducting a research study at Diabetes WA entitled "Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people with type 1 diabetes mellitus?". Ms Brennan has informed Diabetes WA of the workshop content, study design and target population. As intellectual property owners of the program under investigation, Type 1 TACTICS for Exercise, Diabetes WA give permission for the program to be used and evaluated in the above mentioned research project.

Diabetes WA acknowledge the potential impact of this project in upskilling the current diabetes health professional workforce in an area that is currently lacking evidence informed interventions and guidance for diabetes educators. Furthermore, as an organisation supporting the journey of those living with diabetes, we see great value in being able to provide a service to the type 1 diabetes community that is currently missing. In an effort to provide equitable and accessible health services to all people living with diabetes, Diabetes WA will support this research effort and will provide full access to the program and its resources for the successful implementation of this study. In kind support will be offered in areas including marketing, recruitment and venue.

If you have any queries, please do not hesitate to call.

Kind regards

Deborah Schofield
General Manager of Health Services I Diabetes WA
Level 3, 322 Hay St, Subiaco WA 6008
P: 08 9325 7699 I D: 08 9436 6210 I F: 08 9221 1183
E: Deborah.schofield@diabeteswa.com.au

Diabetes WA I Level 3, 322 Hay Street, Subiaco WA 6008 I 172 Campbell Street, Belmont WA 6104
PO Box 1699, Subiaco WA 6904 I p 1300 001 880 I f 08 9221 1183 I e info@diabeteswa.com.au I www.diabeteswa.com.au

D.6 Curtin Human Research Ethics Committee Approval

Curtin University

14-Dec-2018

Name:	Janie Brown
Department/School:	School of Nursing, Midwifery and Paramedicine
Email:	Janie.Brown@curtin.edu.au

Dear Janie Brown

RE: Ethics approval
Approval number: HRE2018-0795

Thank you for submitting your application to the Human Research Ethics Office for the project **Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.**

Your application was reviewed by the Curtin University Human Research Ethics Committee at their meeting on **04-Dec-2018**.

The review outcome is: **Approved.**

Your proposal meets the requirements described in National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007).*

Approval is granted for a period of one year from **04-Dec-2018** to **04-Dec-2019**. Continuation of approval will be granted on an annual basis following submission of an annual report.

Personnel authorised to work on this project:

Name	Role
Brown, Janie	CI
Brennan, Marian	Student
Leslie, Gavin	Supervisor
Ntoumanis, Nikos	Supervisor

Standard conditions of approval

1. Research must be conducted according to the approved proposal
2. Report in a timely manner anything that might warrant review of ethical approval of the project including:
   • proposed changes to the approved proposal or conduct of the study

- unanticipated problems that might affect continued ethical acceptability of the project
- major deviations from the approved proposal and/or regulatory guidelines
- serious adverse events

3. Amendments to the proposal must be approved by the Human Research Ethics Office before they are implemented (except where an amendment is undertaken to eliminate an immediate risk to participants)
4. An annual progress report must be submitted to the Human Research Ethics Office on or before the anniversary of approval and a completion report submitted on completion of the project
5. Personnel working on this project must be adequately qualified by education, training and experience for their role, or supervised
6. Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, that bears on this project
7. Changes to personnel working on this project must be reported to the Human Research Ethics Office
8. Data and primary materials must be retained and stored in accordance with the Western Australian University Sector Disposal Authority (WAUSDA) and the Curtin University Research Data and Primary Materials policy
9. Where practicable, results of the research should be made available to the research participants in a timely and clear manner
10. Unless prohibited by contractual obligations, results of the research should be disseminated in a manner that will allow public scrutiny; the Human Research Ethics Office must be informed of any constraints on publication
11. Ethics approval is dependent upon ongoing compliance of the research with the Australian Code for the Responsible Conduct of Research, the National Statement on Ethical Conduct in Human Research, applicable legal requirements, and with Curtin University policies, procedures and governance requirements
12. The Human Research Ethics Office may conduct audits on a portion of approved projects.

Special Conditions of Approval

This letter constitutes ethical approval only. This project may not proceed until you have met all of the Curtin University research governance requirements.

Should you have any queries regarding consideration of your project, please contact the Ethics Support Officer for your faculty or the Ethics Office at hrec@curtin.edu.au or on 9266 2784.

Yours sincerely

Dr Karen Heslop
Deputy Chair, Human Research Ethics Committee

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D.7 State Health Service Human Research Ethics Committee Approval

SMHS Low Risk Panel
Level 2, Education Building, Fiona Stanley Hospital
14 Barry Marshall Parade
MURDOCH Western Australia 6150

12 March 2019

Ms Marian Brennan
Curtin University
Kent Street
Bentley WA 6102

Dear Ms Brennan

PRN:	RGS0000003164
Project Title:	*Can self-management group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.*
Protocol Number:	V1_25.02.19

Thank you for submitting the above research project for ethical review. The project was considered under the Alternative Review process in accordance with the Committee's Terms of Reference and Standard Operating Procedures.

I am pleased to advise you that the above research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* and ethical approval for this research project has been granted. The South Metropolitan Health Service Human Research Ethics Committee at its meeting to be held on 09 April 2019 will be notified that this project was approved on their behalf.

To find the original letter and any possible attachments, click here when logged into RGS.

The nominated participating sites in this project are:

Armadale Health Service
Bentley Health Service
Fiona Stanley Hospital
Rockingham General Hospital
Royal Perth Hospital
Sir Charles Gairdner Hospital

[Note: If additional sites are recruited prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the Human Research Ethics Committee (HREC). Notification of withdrawn sites should also be provided to the HREC in a timely fashion.]

The approved documents include:

Document	Version	Version Date
Data management plan	2	10/03/2019
Flyer	1	25/02/2019
Posters	1	25/02/2019
Project summary document (Protocol)	2	10/03/2019
Questionnaire T1 control	1	25/02/2019
Questionnaire T1 INT	1	25/02/2019
Randomisation consent	1	25/02/2019

Study design protocol diagram	1	25/02/2019
Thematic analysis protocol	1	10/03/2019
Participant Information Sheet	3	13/02/2019

Ethical approval of this project from SMHS Low Risk Panel is valid from 12 March 2019 to 12 March 2024 subject to compliance with the 'Conditions of Ethics Approval for a Research Project' (Appendix A).

A copy of this ethical approval letter must be submitted by all site Principal Investigators to the Research Governance Office or equivalent body or individual at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate site authorisation has been obtained from the Chief Executive or Delegate of the site under whose auspices the research will be conducted at that site.

Should you have any queries about the SMHS Low Risk Panel's consideration of your project, please contact the Ethics Office at SMHS.HREC@health.wa.gov.au or on 08 6152 2064. The HREC's Terms of Reference, Standard Operating Procedures and membership are available from the Ethics Office or from http://ww2.health.wa.gov.au/About-us/South-Metropolitan-Health-Service/Involving-our-community/Human-Research-Ethics-and-Governance.

The HREC wishes you every success in your research.

Yours sincerely

Kim Crameri
Delegate of the Chair
South Metropolitan Health Service Human Research Ethics Committee

D.8 Curtin Human Research Ethics Committee Amendments

D.8.1 Amendment approval number HRE2018-0795-02

Curtin University

Research Office at Curtin

GPO Box U1987
Perth Western Australia 6845

Telephone +61 8 9266 7863
Facsimile +61 8 9266 3793
Web research.curtin.edu.au

15-Feb-2019

Name: Janie Brown
Department/School: School of Nursing, Midwifery and Paramedicine
Email: Janie.Brown@curtin.edu.au

Dear Janie Brown

RE: Amendment approval
Approval number: HRE2018-0795

Thank you for submitting an amendment request to the Human Research Ethics Office for the project **Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.**

Your amendment request has been reviewed and the review outcome is: **Approved**

The amendment approval number is HRE2018-0795-02 approved on 15-Feb-2019.

The following amendments were approved:

1. Addition of "consent form for randomisation".

2. Addition of 'pregnancy' as an exclusion criteria

3. Addition/amendment to questions within questionnaires at all three time points

Any special conditions noted in the original approval letter still apply.

Standard conditions of approval

1. Research must be conducted according to the approved proposal
2. Report in a timely manner anything that might warrant review of ethical approval of the project including:
   - proposed changes to the approved proposal or conduct of the study
   - unanticipated problems that might affect continued ethical acceptability of the project
   - major deviations from the approved proposal and/or regulatory guidelines
   - serious adverse events
3. Amendments to the proposal must be approved by the Human Research Ethics Office before they are implemented (except where an amendment is undertaken to eliminate an immediate risk to participants)
4. An annual progress report must be submitted to the Human Research Ethics Office on or before the anniversary of approval and a completion report submitted on completion of the project

5. Personnel working on this project must be adequately qualified by education, training and experience for their role, or supervised
6. Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, that bears on this project
7. Changes to personnel working on this project must be reported to the Human Research Ethics Office
8. Data and primary materials must be retained and stored in accordance with the Western Australian University Sector Disposal Authority (WAUSDA) and the Curtin University Research Data and Primary Materials policy
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10. Unless prohibited by contractual obligations, results of the research should be disseminated in a manner that will allow public scrutiny; the Human Research Ethics Office must be informed of any constraints on publication
11. Ethics approval is dependent upon ongoing compliance of the research with the Australian Code for the Responsible Conduct of Research, the National Statement on Ethical Conduct in Human Research, applicable legal requirements, and with Curtin University policies, procedures and governance requirements
12. The Human Research Ethics Office may conduct audits on a portion of approved projects.

Should you have any queries regarding consideration of your project, please contact the Ethics Support Officer for your faculty or the Ethics Office at hrec@curtin.edu.au or on 9266 2784.

Yours sincerely

Amy Bowater
Ethics, Team Lead

D.8.2 Amendment approval number HRE2018-0795-04

Curtin University

18-Apr-2019

Name: Janie Brown
Department/School: School of Nursing, Midwifery and Paramedicine
Email: Janie.Brown@curtin.edu.au

Dear Janie Brown

RE: Amendment approval
Approval number: HRE2018-0795

Thank you for submitting an amendment request to the Human Research Ethics Office for the project **Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.**

Your amendment request has been reviewed and the review outcome is: **Approved**

The amendment approval number is HRE2018-0795-04 approved on 18-Apr-2019.

The following amendments were approved:
Addition of four new images sourced from Diabetes WA (collaborating organisation). The text to accompany these images will remain the same as previously approved text.

Any special conditions noted in the original approval letter still apply.

Standard conditions of approval

1. Research must be conducted according to the approved proposal
2. Report in a timely manner anything that might warrant review of ethical approval of the project including:
   - proposed changes to the approved proposal or conduct of the study
   - unanticipated problems that might affect continued ethical acceptability of the project
   - major deviations from the approved proposal and/or regulatory guidelines
   - serious adverse events
3. Amendments to the proposal must be approved by the Human Research Ethics Office before they are implemented (except where an amendment is undertaken to eliminate an immediate risk to participants)
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8. Data and primary materials must be retained and stored in accordance with the Western Australian University Sector Disposal Authority (WAUSDA) and the Curtin University Research Data and Primary Materials policy
9. Where practicable, results of the research should be made available to the research participants in a timely and clear manner
10. Unless prohibited by contractual obligations, results of the research should be disseminated in a manner that will allow public scrutiny; the Human Research Ethics Office must be informed of any constraints on publication
11. Ethics approval is dependent upon ongoing compliance of the research with the Australian Code for the Responsible Conduct of Research, the National Statement on Ethical Conduct in Human Research, applicable legal requirements, and with Curtin University policies, procedures

and governance requirements

12. The Human Research Ethics Office may conduct audits on a portion of approved projects.

Should you have any queries regarding consideration of your project, please contact the Ethics Support Officer for your faculty or the Ethics Office at hrec@curtin.edu.au or on 9266 2784.

Yours sincerely

Amy Bowater
Ethics, Team Lead

D.8.3   Amendment approval number HRE2018-0795-06

01-May-2019

Name: Janie Brown
Department/School: School of Nursing, Midwifery and Paramedicine
Email: Janie.Brown@curtin.edu.au

Dear Janie Brown

RE: Amendment approval
Approval number: HRE2018-0795

Thank you for submitting an amendment request to the Human Research Ethics Office for the project **Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.**

Your amendment request has been reviewed and the review outcome is: **Approved**

The amendment approval number is HRE2018-0795-06 approved on 01-May-2019.

The following amendments were approved:

1. Expansion of recruitment area from Perth metro only, to Bunbury/Busselton and surrounds.

2. Interviewing a willing project steering group member (who is living with type 1 diabetes) about his type 1 diabetes journey with physical activity to use in local newspapers to raise awareness of our study. Consent will be obtained from the steering group member before proceeding to the newspapers.

Any special conditions noted in the original approval letter still apply.

Standard conditions of approval

1. Research must be conducted according to the approved proposal
2. Report in a timely manner anything that might warrant review of ethical approval of the project including:
    * proposed changes to the approved proposal or conduct of the study
    * unanticipated problems that might affect continued ethical acceptability of the project
    * major deviations from the approved proposal and/or regulatory guidelines
    * serious adverse events
3. Amendments to the proposal must be approved by the Human Research Ethics Office before they are implemented (except where an amendment is undertaken to eliminate an immediate risk to participants)
4. An annual progress report must be submitted to the Human Research Ethics Office on or before the anniversary of approval and a completion report submitted on completion of the project
5. Personnel working on this project must be adequately qualified by education, training and experience for their role, or supervised
6. Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, that bears on this project
7. Changes to personnel working on this project must be reported to the Human Research Ethics Office
8. Data and primary materials must be retained and stored in accordance with the Western Australian University Sector Disposal Authority (WAUSDA) and the Curtin University Research Data and Primary Materials policy

9. Where practicable, results of the research should be made available to the research participants in a timely and clear manner
10. Unless prohibited by contractual obligations, results of the research should be disseminated in a manner that will allow public scrutiny; the Human Research Ethics Office must be informed of any constraints on publication
11. Ethics approval is dependent upon ongoing compliance of the research with the Australian Code for the Responsible Conduct of Research, the National Statement on Ethical Conduct in Human Research, applicable legal requirements, and with Curtin University policies, procedures and governance requirements
12. The Human Research Ethics Office may conduct audits on a portion of approved projects.

Should you have any queries regarding consideration of your project, please contact the Ethics Support Officer for your faculty or the Ethics Office at hrec@curtin.edu.au or on 9266 2784.

Yours sincerely

Amy Bowater
Ethics, Team Lead

D.8.4 Amendment approval number HRE2018-0795-08

Curtin University

Research Office at Curtin

GPO Box U1987
Perth Western Australia 6845

Telephone +61 8 9266 7863
Facsimile +61 8 9266 3793
Web research.curtin.edu.au

16-Sep-2019

Name: Janie Brown
Department/School: School of Nursing, Midwifery and Paramedicine
Email: Janie.Brown@curtin.edu.au

Dear Janie Brown

RE: Amendment approval
Approval number: HRE2018-0795

Thank you for submitting an amendment request to the Human Research Ethics Office for the project **Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.**

Your amendment request has been reviewed and the review outcome is: **Approved**

The amendment approval number is HRE2018-0795-08 approved on 16-Sep-2019.

The following amendments were approved:
1. Update details on semi-structured focus group schedule.
2. Provide an additional demographic questionnaire for focus group participants

Any special conditions noted in the original approval letter still apply.

Standard conditions of approval

1. Research must be conducted according to the approved proposal
2. Report in a timely manner anything that might warrant review of ethical approval of the project including:
   - proposed changes to the approved proposal or conduct of the study
   - unanticipated problems that might affect continued ethical acceptability of the project
   - major deviations from the approved proposal and/or regulatory guidelines
   - serious adverse events
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and governance requirements
12. The Human Research Ethics Office may conduct audits on a portion of approved projects.

Should you have any queries regarding consideration of your project, please contact the Ethics Support Officer for your faculty or the Ethics Office at hrec@curtin.edu.au or on 9266 2784.

Yours sincerely

Amy Bowater
Ethics, Team Lead

D.9   Participant Information Statements

D.9.1   Randomised Controlled Trial

Addressing Barriers to Physical Activity in Type 1 Diabetes

PARTICIPANT INFORMATION STATEMENT

HREC Project Number:	HRE2018-0795
Project Title:	*Can self-management group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.*
Chief Investigator:	*Dr Janie Brown* *Senior lecturer (Curtin University), Course Coordinator (Master of Nursing Practice), Higher Degree by Research Supervisor (PhD and MPhil)*
Student researcher:	*Marian Brennan*
Version Number:	*3*
Version Date:	*13/02/2019*

What is the Project About?
Physical activity is often recommended to people living with Type 1 Diabetes (T1D) in an effort to reduce the risk of long-term complications associated with T1D, improve insulin requirements and improve well-being. Although beneficial, we know that as a whole, people living with T1D are less active than the general population. Research suggests these differences in physical activity may be due to specific barriers experienced by people living with T1D. We believe existing physical activity promotion initiatives for the general population do not take into account the complex factors affecting people with T1D. Currently, there are no researched programs to help people with T1D become more physically active.

This project is designed to see if a group education program, Type 1 TACTICS for Exercise helps people living with T1D overcome fear of hypoglycaemia as a barrier to physical activity. The project is based on previous exploratory work done at Curtin University and Diabetes WA in 2017. The study will involve approximately 120 adults living with T1D. If we can help people with T1D become more physically active, we may reduce the incidence of diabetes related complications and improve the lives of people living with the condition.

Who is doing the Research?
The project is being conducted by Curtin University and Diabetes WA. The research project is being conducted by Marian Brennan as part of her Doctor of Philosophy at Curtin University studies and is funded through the University. Diabetes WA have agreed to support the project. Marian is supervised by three experienced researchers from Curtin University, Dr Janie Brown, Prof. Gavin Leslie and Prof. Nikos Ntoumanis.

Why am I being asked to take part and what will I have to do?
We are looking for adults aged between 18-65 years who have lived with T1D for greater than 6 months and who did NOT participate in our research in 2017.

Participation in the project will involve being randomly allocated to either Group 1 or Group 2. This will be done by chance, like tossing a coin. Neither you nor the researcher can choose which group you go in. Each of these groups will be asked to attend an education session - part one and an education session - part two, four weeks later. Part one will run for **one to three hours** and part two for **one hour**. These group sessions will be held in north, south and central locations around Perth, Western Australia. We will make digital video recording of each group for the purposes of assessing the facilitator. A trained facilitator assessor from Diabetes WA will view the recording for assessment purposes only.

We will ask you (regardless of the group you are allocated to) to complete a questionnaire upon arriving to group session - part one and two. A third questionnaire will be sent to you eight weeks later. You will be asked to consider questions relating to your diabetes such as how long you have had it and how it makes you feel day to day. You will also be asked questions relating to physical activity such as how much you currently do, how you feel about physical activity and what difficulties you have in participating in physical activity. The questionnaires will be completed on supplied electronic tablet devices (ipads) at part – one and part – two and will be sent to you via email or SMS link at eight weeks following part two. We are happy to provide paper questionnaires if you prefer this method. Each questionnaire will take approximately 15 minutes to complete.

Following the completion of the final questionnaire, you will be asked to return to participate in a focus group. This focus group gives you an opportunity to let us know what you thought of the sessions, what aspects were helpful and what aspects were less helpful. We would also like to know how and why these aspects were either helpful or not. Focus groups will be held north, south and central to Perth. We will make a digital audio recording so we can accurately recall conversations to identify any common themes brought up in each group. After the focus group we will make a full written copy of the recording.

Are there any benefits' to being in the research project?
The results of this study will help us find acceptable and effective programs to help people living with type 1 diabetes, become more active. We believe this has great potential to improve the health and well-being of people living with type 1 diabetes across Australia. As a participant in this project, you will have the opportunity to meet and interact with other adults living with T1D who may also share some common interests and challenges. Sometimes, people appreciate the opportunity to discuss their opinions, feelings and their condition with others experiencing similar things. You will also be given the opportunity to learn about physical activity and how to participate safely. There will be no costs to you and you will be offered a Coles Myer gift card and a resistance training band in acknowledgement of your support for the study.

Are there any risks, side-effects, discomforts or inconveniences from being in the research project?
Apart from giving up your time, we do not expect that there will be any risks or inconveniences associated with taking part in this study. We hope that the provided Coles Myer voucher helps compensate you for any parking costs you may incur while taking part in the study. We have been careful to make sure that the questions in the questionnaire do not cause you any distress, but if you feel anxious about any of the questions you do not need to answer them. If the questions cause any concerns or upset you, we can refer you to an appropriate professional counsellor through **Diabetes WA (1300 001 880)** or please call **Lifeline 13 11 14**.

Although we will discuss strategies to minimise these risks, undertaking physical activity which you are not accustomed to, may increase your risk of muscle soreness or injury. For people living with type 1 diabetes, physical activity can also increase the risk of hypoglycaemia. Both study groups will have access to information to help minimise these risks.

If the findings of the study suggest one form of program to be more effective than the other, those who were not in the most effective group will be given the opportunity to attend the alternate group following the completion of the project. You will be free to continue receiving your usual diabetes care during the course of the project.

Who will have access to my information?
The information collected in this research will be non-identifiable (anonymous). This means that we do not need to collect individual names. We may ask you to create a unique code on your questionnaires so we can determine how your responses might have changed over time. No one, not even the research team, will be able to identify your information. The following people will have

Participant Information Form Version 3, 13/02/2019
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access to the information we collect in this research: the research team and, in the event of an audit or investigation, staff from the Curtin University Office of Research and Development.

The information we collect in this study will be kept under secure conditions at Curtin University for 25 years after the research is published and then it will be destroyed. Electronic data will be password-protected and hard copy data (including video or audio tapes) will be kept in locked storage.

The results of this research may be presented at conferences or published in professional journals. You will not be identified in any results that are published or presented. Whilst all care will be taken to maintain privacy and confidentiality of any information shared at a focus group or group discussion, you should be aware that you may feel embarrassed or upset if one of the group members repeats things said in a confidential group meeting.

Will you tell me the results of the research?
We will write to you at the end of the research (in about 24 months) and let you know the results of the research. Results will not be individual but based on all the information we collect and review as part of the research. Results may also be available from Diabetes WA e-newsletters, social media pages and publications.

Do I have to take part in the research project?
Taking part in a research project is voluntary.

Can I change my mind?
If you decide to take part and then change your mind, that is okay, you can withdraw from the project. If you choose not to take part or start and then stop the study, it will not affect your relationship with the University or Diabetes WA.

It must be noted that in an anonymous questionnaire (like we are using) you can withdraw prior to submitting your questionnaire. However, as data are anonymous we may not be able to withdraw your response once it has been submitted. We will be unable to destroy your specific information because it has been collected in an anonymous way.

What happens next and who can I contact about the research?
If you decide to take part in this research we will ask you to sign the consent form. By signing it is telling us that you understand what you have read and what has been discussed. Signing the consent indicates that you agree to be in the research project and have your health information used as described. Please take your time and ask any questions you have before you decide what to do. You will be given a copy of this information and the consent form to keep.

Ms Marian Brennan
PhD Candidate
1300 001 880
marian.brennan@postgrad.curtin.edu.au

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2018-0795). Australian New Zealand Clinical Trials Registry (ANZCTR) registration number ACTRN12618001729213p. Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.

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D.9.2 Focus Groups

Participant Information Statement - Focus Groups

Dear research participant,

Thank you for your participation in the research project thus far. The questionnaires you have completed as part of the initial phase of the study will help us understand how to help people with type 1 diabetes overcome fear of hypoglycaemia as a barrier to physical activity. So that we can improve our understanding of some of the preliminary results of these questionnaires, we would like to invite you to take part in the second phase of the research study.

Participation in this phase of the study involves attending a focus group where you will be asked about what you thought of the sessions you attended in the first phase of the study, what aspects were helpful and what aspects were less helpful. We would also like to know how and why these aspects were either helpful or not. Focus groups will be held north, south and central to Perth. We will make a digital audio recording so we can accurately recall conversations to identify any common themes brought up in each group. After the focus group we will make a full written copy of the recording. Please complete and return the attached consent form to the focus group facilitator.

Your answers to the focus group questions are completely confidential and there are no right or wrong answers. Your participation is voluntary and your decision whether or not to participate will not have any negative effect on your existing relationship with Diabetes WA or Curtin University. You are free to withdraw from participation at any time.

The results of this focus group will help us to better understand the best way to help those living with type 1 diabetes, overcome fear of hypoglycaemia as a barrier to physical activity. The results of this study may be published in a peer-reviewed journal and presented at conferences, but only group data will be reported. As the focus group participation is completely confidential you will not be identifiable in these publications or presentations. Data (both audio files and transcripts) will be stored for 25 years after completion of the project in accordance with the joint NHMRC/AVCC Statement and Guidelines on research (1977). Access will only be available to the researchers.

Curtin University Human Research Ethics Committee (HREC) has approved this study (HRE2018-0795). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.

If you have any questions or if you would like to know the results of the study, please e-mail Marian Brennan - marian.brennan@diabeteswa.com.au

CONSENT FORM

Title of research project: Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.

Name of researcher: Marian Brennan

Tick the box that applies, sign and date and give to the focus group facilitator.

I agree to take part in the research project specified above.	☐Yes ☐No
I understand the information about my participation in the research project, which has been provided to me by the researchers.	☐Yes ☐No
I understand that my participation is voluntary and I understand that I can cease my participation at any time.	☐Yes ☐No
I understand that my participation in this research will be treated with confidentiality.	☐Yes ☐No
I understand that focus group will be recorded	☐Yes ☐No
I understand that any information that may identify me will be de-identified at the time of analysis of any data.	☐Yes ☐No
I understand that no identifying information will be disclosed or published.	☐Yes ☐No
I understand that information gathered in this part of the research project will be kept confidentially for 25 years at the University.	☐Yes ☐No
I am aware that I can contact the researchers at any time with any queries. Their contact details are provided to me.	☐Yes ☐No
I understand that this research project has been approved by the Curtin University Human Research Ethics Committee.	☐Yes ☐No

Participants name: _____

Participants signature: _____

Date: _____

D.10   Consent for Randomisation

CONSENT FOR RANDOMISATION

Title of research project: Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.

Name of researcher: Marian Brennan

Tick the box that applies, sign and date and give to the group facilitator.

I agree to take part in the research project specified above.	☐Yes ☐No
I understand the information about my participation in the research project, which has been provided to me by the researchers.	☐Yes ☐No
I understand that my participation is voluntary and I understand that I can cease my participation at any time.	☐Yes ☐No
I understand that my participation in this research will be treated with confidentiality.	☐Yes ☐No
I understand I will be randomly allocated to one of two groups and I cannot choose which group to go in.	☐Yes ☐No
I understand that the workshop will be recorded	☐Yes ☐No
I understand that any information that may identify me will be de-identified at the time of analysis of any data.	☐Yes ☐No
I understand that no identifying information will be disclosed or published.	☐Yes ☐No
I understand that all information gathered (including digital recordings) in this research will be kept confidentially at the University for 25 years from publication.	☐Yes ☐No
I am aware that I can contact the researchers at any time with any queries. Their contact details are provided to me.	☐Yes ☐No
I understand that this research project has been approved by the Curtin University Human Research Ethics Committee.	☐Yes ☐No

Participants name: _____

Participants signature: _____

Date: _____

☐ Please tick this box and provide your email or mail address below if you wish to receive feedback about the research.

Email: _____

D.11   Data Management Plan

Curtin University

Research Data Management Plan
_____

Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.

Supervisor	Janie Brown
Data Management Plan Edited by	Marian Brennan
Modified Date	10/03/2019
Data Management Plan ID	BROWNJ-HS05224
Faculty	Health Sciences

1   Research Project Details

1.1   Research project title

Can self-management, group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.

1.2   Research project summary

Aim: To evaluate feasibility and reliability of a group education intervention designed to reduce Fear of Hypoglycaemia (FoH) as a barrier to Physical Activity (PA) in adults living with Type 1 Diabetes (T1D).

Background: Type 1 diabetes is a complex auto-immune condition requiring ongoing self-management. Physical activity is a recommended management strategy for T1D, however it often provokes drastic excursions in blood glucose levels – specifically hypoglycaemia. Physical activity rates in T1D are low and thought to be associated with the most cited barrier to PA in this population, FoH. There are no evidence informed interventions available to address this barrier to PA.

Study design: Mixed methods randomised control feasibility study design. The intervention is a three hour self-management group education workshop (Part I) with a one hour booster workshop four weeks after part 1. Control will consist of a one-hour general information session followed by a review information session four weeks later. Approximately three focus groups for each arm will then be conducted.

Sampling: Convenience sampling will be used to recruit participants for the quantitative component of the study. Participants will be adults aged between 18-65, living with type 1 diabetes in Perth, Western Australia. The sample will be selected for feasibility rather than powered outcomes. Further purposive sampling of the participants will then be employed to form focus groups.

Data collection: Questionnaires will be administered to both groups immediately pre part I, immediately pre part II and eight weeks post part II. Questionnaires will gather data relating to barriers to physical activity, attitudes, intentions and self-efficacy towards physical activity, self-reported physical activity rates, diabetes distress and well-being.

Data Analysis: Within and between group comparisons of quantitative data will be analysed using methods recommended in the literature of each respective validated tool. Qualitative focus group data will be subject to thematic analysis.

Significance: Decreasing the strongest barrier to PA experienced by people living with T1D has the potential to lead to increased rates of PA. A more active type 1 population is likely to lead to decreased diabetes related complications and improved well-being for those living with the condition.

1.3   Keywords
Type 1 diabetes, Physical activity, Barriers to physical activity, Fear of hypoglycaemia, Self-management education

2   Research Project Data Details

2.1 Research project data summary

Quantitive data collection will involve administering a questionnaire at three time points to a control and intervention arm - Immediately pre intervention/control part I, Immediately pre intervention/control part II and eight weeks post intervention/control part II. The questionnaire will be administered online, electronically at all three time points.

The questionnaire will be a composite of the following validated questionnaires; - Barriers to Physical Activity in Diabetes - 1 - International Physical Activity Questionnaire - short form - WHO-5 Well-being index - Problem Areas in Diabetes scale - A scale was developed using Fishbein and Ajzen (2010) guidelines in order to measure attitudes and intentions towards PA. - Self-efficacy measure for PA and for managing BGLs surrounding PA was developed using Bandura's guide for constructing self-efficacy scales (Bandura, 2006). - General and diabetes specific demographic questions will also be included in the questionnaire.

Qualitative data collection will include a total of 6 focus groups. Groups will be audio recorded and then transcribed. Recording applications on iPhone 8 iOS 11.4 or above will be used to record focus groups.

2.2 Will the data be identifiable

- Non-identifiable — data which has never been labelled with individual identifiers

2.3 Will data, including biospecimens, be sent overseas?

No

2.4 Data organisation and structure

Quantitative data will be stored on Qualtircs and downloaded and saved as Excel 2010 xlsx format - raw*dataset*_ddmmyyyy.

The questionnaire analysis file will be worked on and updated regularly. Weekly snapshots of the data file will be made, and each snapshot will be date stamped for easy identification - analysis *file*ddmmyyyy.xlsx

Voice recordings will be stored as MP3 files and named FocusGroup#*dd*mmyyyy Transcripts will be stored as Word documents and named FocusGroup#*transcriptddmmyyy Video recordings will be stored as MP4 files and named Intervention#ddmmyyy or control#_ddmmyyy*

Any paper copy questionnaires will be stored in intervention or control group folders, stored in subgroups of attended workshops.

3 Research Project Data Storage, Retention and Dissemination Details

3.1 Storage arrangements

For the duration of the project, the physical data sheets will be stored in a locked filing cabinet in the investigator's office at Curtin University, Bentley. When electronic field questionnaire is complete, the data will be transferred to the Curtin R drive, which is set up according to standard Curtin Information Technology Services security and safeguarding protocols. Weekly snapshots of the survey data analysis file will be made and stored on the R drive. Data will continue to be stored at Curtin University, Bentley for 25 years following the project completion after which time the data will be destroyed.

Upon project completion, the principal investigator will work with Curtin Information Management and Archives to find a suitable long-term (25 year) storage location.

3.2 Estimated data storage volume

Approximately 8GB - text files and compressed MP3 files only. Approximately 170GB - video MP4 files

3.3 Safeguarding measures