

School of Population Health

Investigating Medication Adherence: A Mixed Methods Study

Caitlin Rose Liddelow

ORCID: 0000-0003-1083-5979

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

February 2021

Declaration

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

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

Human Ethics: 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 March 2014. The proposed research study received human research ethics approval from the Curtin University Human Research Ethics Committee (EC00262): Approval numbers HRE2017-0173 and HRE2020-0158.

Signature:

Date: 1st February 2021

Acknowledgement of Country

We acknowledge that Curtin University works across hundreds of traditional lands and custodial groups in Australia, and with First Nations people around the globe. We wish to pay our deepest respects to their ancestors and members of their communities, past, present, and to their emerging leaders. Our passion and commitment to work with all Australians and peoples from across the world, including our First Nations peoples are at the core of the work we do, reflective of our institutions' values and commitment to our role as leaders in the Reconciliation space in Australia.

Acknowledgements

I would first like to thank my wonderful and incredibly supportive supervisors, Professor Barbara Mullan and Associate Professor Mark Boyes. It's been a big three years and I would not have made it through without you both. Barbara, you're the one that started it all. Thank you for initiating my interest in research pushing me to apply to do a PhD, I will forever be thankful. Mark, thank you for coming on board in 2018 and providing a different view on things. Your terrible Dad jokes, even though most of them I didn't understand, will forever be a great memory of supervision. To you both, thank you for always telling me how it is, believing in me when I felt defeated and for being wonderful role models to me.

Thank you to the Australia Government for funding two years of my research through the Research Training Scholarship, to all the people who participated in my studies, and to Hannah McBride for her assistance and support with the qualitative analysis and interpretation. You are a life saver, Hannah! To my wonderful Curtin support network, Ashley Slabbert, Emily Jones, Kate Tonta, Lexy Staniland, Danyelle Greene and the rest of "The Hubbies", the numerous laughs, chats, vent sessions, tears, coffees, and most of all, the popcorn with chicken salt, has helped me get through each day of the past three years. To my health psychology lab group, in particular Lisa Novoradovskaya and Jessica Charlesworth, thank you for also always supporting me and checking in when needed. You are both special friends.

Now to my non-Curtin friends and family. To my parents, Glen and Leona, thank you for your unwavering support in everything I do. Thank you for attempting to read my work despite having no clue what I'm talking about and thank you for always pushing me to achieve my best. To my brother, Jaxon, thanks for not being the worst younger brother out there and for supporting me when you felt like it. To my closest friends, I'm sorry I've been absent for a few years now but I'm back and more confident than ever. I would particularly like to thank Kasey Gordon, Brianna Carey, Paris Matthews, Asha Back, Kirstie Harrison, Ellie Neretlis, and Beth Juniper for checking in and listening to be vent for the past seven years. I'm lucky to call you all my closest friends and pushing me when I needed it most.

List of Papers

Journal Articles (* included in the thesis)

- Mullan, B., **Liddelow, C.**, Charlesworth, J., Slabbert, A., Allom, V., Harris, C., Same, A., & Kothe, E (2021). Investigating mechanisms for recruiting and retaining volunteers: The role of habit strength and planning in volunteering engagement. *The Journal of Social Psychology*, 161(3), 363-378. <https://doi.org/10.1080/00224545.2020.1845113>
- ***Liddelow, C.**, Mullan, B., & Boyes, M. (2020). The roles of health literacy and knowledge in adherence to the oral contraceptive pill. *Health Psychology and Behavioural Medicine*, 8(1), 587-600. <https://doi.org/10.1080/21642850.2020.1850288>
- ***Liddelow, C.**, Mullan, B., Boyes, M. & McBride, H. (2020). A qualitative application of Temporal Self-Regulation Theory to understand adherence to simple and complex medication regimens. *Healthcare*, 8(4), 487. <https://doi.org/10.3390/healthcare8040487>
- Mullan, B., Green, A., Baughman, F., Charlesworth, J., Franz, T., Haywood, D., **Liddelow, C.**, McAlpine, T., Mergelsberg, E., & Novoradovskaya, E. (2020). Investigating habit changes in lockdown: A COVID-19 study of self-care at home. *Health Psychology Update*, 29 (Special Issue), 52-53.
- ***Liddelow, C.**, Mullan, B., & Boyes, M. (2020). Understanding the predictors of medication adherence: Applying Temporal Self-Regulation Theory. *Psychology and Health*, 36(5), 529-548. <https://doi.org/10.1080/08870446.2020.1788715>
- Judah, G., Mullan, B., Yee, M., Johansson, L., Allom, V., & **Liddelow, C.** (2020). A Habit-Based Randomised Controlled Trial to Reduce Sugar-Sweetened Beverage Consumption: The Impact of the Substituted Beverage on Behaviour and Habit Strength. *International Journal of Behavioral Medicine*, 27(6), 623-635. <https://doi.org/10.1007/s12529-020-09906-4>
- Same, A., McBride, H., **Liddelow, C.**, Mullan, B., & Harris, C. (2020). Motivations for volunteering time with older adults: A qualitative study. *PLoS ONE*, 15(5), e0232718. <https://doi.org/10.1371/journal.pone.0232718>
- Liddelow, C.**, Mullan, B., & Novoradovskaya, E. (2020). Exploring medication adherence among Australian adults using an extended theory of planned behaviour. *International Journal of Behavioral Medicine*, 27(4), 389-399. <https://doi.org/10.1007/s12529-020-09862-z>
- Same, A., Mullan, B., Harris, C., **Liddelow, C.**, & Slabbert, A. (2019). *Volunteering Trends Study*. Perth, Western Australia: Chorus

List of Conference Presentations

(* presenting thesis findings)

- ***Liddelow, C.**, Mullan, B., & Boyes, M. (Cancelled – COVID-19). *The roles of regimens, habits, cues, and self-regulation in determining prescription medication adherence: A qualitative exploration*. Presented at: 16th International Congress of Behavioural Medicine, Glasgow, Scotland, 19-22 August 2020.
- ***Liddelow, C.**, Mullan, B., & Boyes, M. (2020). *Understanding the predictors of medication adherence: Applying Temporal Self-Regulation Theory*. Mark Liveris Research Student Seminar, Faculty of Health Sciences, Curtin University, May 2020.
- ***Liddelow, C.**, Mullan, B., & Boyes, M. (2020). *What are we actually measuring when we measure medication adherence? An application of Temporal Self-Regulation Theory*. Australasian Society of Behavioural Health and Medicine (ASBHM) Conference, Sydney, Australia, 5-7 February 2020.
- McAlpine, T., Mullan, B., & **Liddelow, C.** (2020). *Exploring the role of environmental cues in sugar-sweetened beverage consumption using a Temporal Self-Regulation Theory framework*. Australasian Society of Behavioural Health and Medicine (ASBHM) Conference, Sydney, Australia, 5-7 February 2020.
- ***Liddelow, C.**, Mullan, B., & Boyes, M. (2019). *Using the Temporal Self-Regulation Theory to understand the predictors of medication adherence*. Australasian Society of Behavioural Health and Medicine (ASBHM) Conference, Christchurch, New Zealand, 13-15 February 2019.
- Moran, A., Mullan, B., & **Liddelow, C.** (2019). *Exploring Temporal Self-Regulation Theory to predict sugar-sweetened beverage consumption*. Australasian Society of Behavioural Health and Medicine (ASBHM) Conference, Christchurch, New Zealand, 13-15 February 2019.
- Liddelow, C.**, & Mullan, B. (2018). *Can an extended model of health behaviour improve prediction of medication adherence? 29th International Congress of Applied Psychology Conference (ICAP)*, Montreal, Canada, 26-30 June 2018.

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Summary/Abstract

Non-adherence to prescription medication is a global concern, with approximately 50% of individuals with a chronic illness reporting non-adherence to their medication. This figure is likely to be higher for individuals taking preventative medications. Temporal Self-Regulation Theory is a theory of behaviour that has yet to be applied to medication adherence but has shown potential in other health behaviours. In this thesis, Temporal Self-Regulation Theory was explored in medication adherence, to further understand the malleable predictors of medication adherence and secondly, how these may assist in improving adherence. To address these aims, the five studies employed different methodologies, such as meta-analytic, quantitative, qualitative, and experimental.

In the first study, a meta-analysis of the individual associations between the three Temporal Self-Regulation Theory constructs (intention, behavioural prepotency, and self-regulatory capacity) and medication adherence was conducted. All three constructs were shown to be weakly-to-moderately significantly associated with medication adherence, however it was identified that different measures of medication adherence, whether they are attitude/belief based or behaviour based, moderated the associations. No studies in the meta-analysis assessed all three constructs in the theory or applied the theory, and therefore the interactions within the theory could not be explored. In study two, a prospective two-part study was conducted to explore the predictive ability of the theory in medication adherence using two different measures of adherence (one attitudes/beliefs based, and the other behaviour based). The theory was partially supported and predicted between 21% - 52%

of the variance in adherence. Cues were the only significant predictor when using the two measures of adherence. The third study was a qualitative study conducted to further test the applicability of the theory. The findings also partially supported the theory with cues identified as important in simple medication regimens and planning important in more complex medication regimens. Additional themes not related to the theory were also identified, including the importance of knowledge and information.

In study four the focus deviated from theory testing to now identifying adherence variance within a population so that an intervention to improve adherence could be targeted. A cross-sectional survey was conducted to ensure adherence varied in our chosen population, women taking the oral contraceptive pill. Health literacy and knowledge were also explored after previous evidence highlighted their importance. It was shown that adherence in this population varied, but also that health literacy and knowledge are important in adherence to the pill. In the final study, a simple intervention was conducted to improve adherence to the oral contraceptive pill. Cues and knowledge, both previously identified as being important, were manipulated and adherence (using two different self-report measures), habit strength and cues were measured at baseline and six-weeks later. The intervention was unsuccessful in changing adherence behaviour, but all four intervention conditions reported increases in habit strength.

Overall, the results of the five studies provide partial support for the use of Temporal Self-Regulation Theory in medication adherence, but also provide further understanding of the role of both malleable factors and individual differences in medication adherence. Future research needs to continue

exploring the applicability of the theory in medication adherence, but to more specific medications or regimens. More research is also needed to better understand the modes and methods to assessing adherence using self-report measures.

Author's Note

This thesis is presented as a hybrid thesis, which includes papers which have been submitted or accepted for publication. As each chapter is a standalone manuscript there is some unavoidable repetition throughout the thesis, particularly when describing the background and rationale of each paper. Considering this, efforts have been made to reduce repetition throughout the introduction and general discussion. Each chapter is presented with a short introduction linking the individual chapters to create a cohesive body of work. Additionally, reference lists have been removed from all papers and presented together at the end of the thesis to increase cohesiveness. Chapter results are all derived from different data sets, from different populations.

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Chapter 1: Introduction to Thesis

Introduction to Chapter 1

In chapter one, I will provide an in-depth explanation of the background and literature of this thesis. First, I will introduce and highlight the current global problem of non-adherence to prescription medications by discussing the issue and providing relevant statistics related to the prevalence of non-adherence. Second, I will identify and discuss the determinants of medication adherence or the lack thereof that have been identified in previous research, particularly social constructs (e.g., ethnicity, cost of medication) and demographics (e.g., age, gender). Thirdly, I will summarise and discuss what research has been previously conducted in attempts to improve adherence. In this section, I will specifically explore the use of health psychology theories. Fourth, I will highlight why previously applied theoretical models of behaviour do not adequately predict variance in medication adherence. I will then introduce the theoretical background of this thesis, Temporal Self-Regulation Theory (Hall & Fong, 2007), which may be able to overcome the issues identified with other theories. I will discuss the psychosocial constructs that form the theory, how the theory is proposed to operate and previous research that has applied it. I will then conclude this chapter by defining the overarching aims and outline of the thesis, as well as the specific focus of each thesis chapter.

Medication Non-Adherence

Medication adherence is a complex behaviour and commonly refers to the extent to which an individual's medication-taking behaviour aligns with the recommendations agreed upon with their health professional (De Geest & Sabaté, 2003). Although there is a commonly used definition in research, there are numerous other, more comprehensive, definitions of medication adherence (Cramer et al., 2008; Morrison et al., 2015) in the literature. Furthermore, the term 'adherence' is often interchanged with 'compliance' in some research, however, the term 'adherence' is preferred as it assumes joint decision making, whereas 'compliance' often implies that the individual is rather complying with a command (Brown & Bussell, 2011; Steiner & Earnest, 2000). Non-adherence to medication can include behaviours such as missing doses (whether purposely or forgetting), taking too much or too little of the medication at one time, not taking the medication dose according to special instructions (e.g., take at the same time every day) or not picking up the medication prescription from the pharmacy (Shrank et al., 2010). Medication adherence is often categorised into two broad types: intentional and non-intentional adherence. Intentional medication non-adherence is when an individual makes the conscious deliberate decision to not take their medication. Non-intentional medication adherence is when the individual simply forgets to take their medication dose/s (Clifford et al., 2008).

Research and government statistics show that in high-income countries such as Australia and the United States, it is estimated that only approximately 50% of adults experiencing chronic illness adhere to their medication as prescribed (De Geest & Sabaté, 2003). It is suggested that in low-income

countries the incidence of medication non-adherence is likely to be even greater due to limited health care facilities and services in some communities, as well as inequality in both accessing health care and obtaining medications in these countries (De Geest & Sabaté, 2003). In medications that are preventative or prophylactic in nature and therefore do not provide instant relief or control of symptoms, adherence is even poorer and more of a challenge to overcome (Walker et al., 2006). The incidence of medication non-adherence has increased in recent years, largely due to the ageing population and the increase in comorbid chronic diseases (Christensen et al., 2009; Fernandez-Lazaro et al., 2019).

Medication adherence is a global problem for many reasons, including but not limited to; greater burden on healthcare systems, increased experience of negative symptoms, increased likelihood of experiencing comorbid diseases, negative impacts on individual health outcomes and a greater chance of mortality (Chisholm-Burns & Spivey, 2012; Cutler et al., 2018). Medication adherence is also costly to not only the individual but also Governments. According to a review conducted by Cutler et al. (2018), in the United States alone medication non-adherence costs between US\$ 5,271 and US\$ 52,341 per patient annually. The cost of non-adherence varies depending on the disease, with cancer, osteoporosis, diabetes, and mental health costing the most. In Australia in 2013, it was estimated that medication non-adherence costs the public healthcare system AU\$ 1.2 billion annually (Roughead et al., 2013). No more up to date figures are available. Similarly, it is estimated that approximately 4% of all hospital admissions in four continents (specifically North America, Europe, Asia and Australia) are the direct result of medication

non-adherence (Mongkhon et al., 2018). In comparison, individuals who are adherent to their prescription medication are three times more likely to experience positive health outcomes, reduced healthcare costs overall and live a happier, more fulfilling life (Chisholm-Burns & Spivey, 2012; DiMatteo et al., 2002). Therefore, given all of this and the positives associated with adherence to medication regimens, understanding medication adherence and improving the current rates of adherence are important avenues to research.

What Influences Medication Adherence?

Numerous reasons and factors for why people do not adhere to their medication have been highlighted in previous research. Firstly, some of these factors can be attributed to the medication itself and the medication regimen often referred to as therapy or disease-related factors (De Geest & Sabaté, 2003). The complexity of the medication regimen has been shown to be negatively associated with medication adherence such that when regimens are more complex (i.e. multiple medications at various times of the day) adherence is likely to be worse (George et al., 2004; Pantuzza et al., 2017). Similarly, side effects of medications have been shown to be related to poorer adherence, particularly in chronic diseases such as diabetes (Chao et al., 2007), hypertension (Van Der Laan et al., 2017), human immunodeficiency virus (HIV; Ammassari et al., 2001; Bartlett, 2002), and schizophrenia (DiBonaventura et al., 2012) where participants that reported experiencing side effects also reported poorer adherence.

Secondly, some barriers to medication adherence can be the result of social or economic factors, such as ethnicity and socioeconomic status. With regards to ethnicity, a review of systematic reviews has shown that minority

ethnic groups, living in mainly ‘Anglo-Saxon’ countries, are likely to be less adherent to their medication compared to other ethnic groups particularly in arthritis, cardiovascular disease and HIV (Gast & Mathes, 2019). There is also some evidence to suggest that socioeconomic status (not including insurance status) is positively related to medication adherence, with individuals in higher socioeconomic income brackets reporting better adherence (Alsabbagh et al., 2014; Gast & Mathes, 2019). These two identified barriers often overlap such that individuals or groups in lower socioeconomic income brackets are often also members of ethnic minority groups (McQuaid & Landier, 2018; Salt & Frazier, 2011; Simoni et al., 2012), largely due to structural inequalities in society. The disparity in adherence, specifically the lower reported adherence in these groups, is likely to be influenced by the mistrust that minority groups have in health providers, the experience of discrimination and systematic inequalities in health care systems (Simoni et al., 2012; Thrasher et al., 2008).

Thirdly, health care system-related factors, specifically the cost of medications, is often expressed as a barrier to medication adherence with individuals paying large amounts for their medications less likely to be adherent (Kelly et al., 2014). However, it does seem as though cost is much more of a barrier to medication adherence in the US compared to other countries such as Australia where the cost of medications are largely subsidised (Kelly et al., 2014).

Finally, patient-related factors are those that are specific to the individual and concern age, gender, comorbidity of diseases (De Geest & Sabaté, 2003) and individual differences such as cognition, education, and health literacy (Martin et al., 2005). There is conflicting evidence regarding the

influence of age on medication adherence and is suggested to vary according to the disease (Gast & Mathes, 2019), however, there is a consensus that there is a positive association between age and adhering to medication. For example, a 2012 systematic review found that adults with HIV below the age of 45 years were less likely to adhere compared to those over 45 years of age (Gemedu et al., 2012). Furthermore, with regards to gender, it has been established that men are more likely to be adherent to their medications compared to women, with this possibly due to women having a greater chance of experiencing chronic diseases and thus more complex medication regimens (Granger et al., 2009; Manteuffel et al., 2014). Comorbidity of diseases, specifically comorbidity with mental health problems, has shown to be negatively associated with medication adherence such that the more chronic diseases an individual is experiencing, the poorer their adherence (Chen et al., 2015; Daley et al., 2012).

Some of the main patient-related factors that have been shown to influence adherence are cognition, education, and health literacy. Individuals need to have a basic understanding of the adherence guidelines suggested by their health professional to effectively adhere (Martin et al., 2005). Health literacy, which refers to having the competency, knowledge, and understanding of basic health recommendations, has been shown to influence medication adherence such that having higher health literacy levels is positively associated with better adherence (Berkman et al., 2011). The inability to read means that simple medical instructions and guidelines are misunderstood or ignored (Martin et al., 2005). Similarly, individuals with impairments affecting their

memory or executive functioning often exhibit lower levels of adherence (Hinkin et al., 2004; Insel et al., 2006).

It is evident that there is a multitude of factors that can influence adherence to medications, however, unfortunately, many of these factors (e.g., ethnicity, age) are not malleable (Kronish & Ye, 2013). Malleability refers to a factor that can be changed or altered and is not permanent. An example of malleable constructs are beliefs and attitudes. Research has shown that beliefs and attitudes are malleable and can be changed through interventions (Lee et al., 2014). Therefore, despite the large amounts of research into the non-malleable factors associated with medication adherence, there has been little improvement in the rates of adherence (Zullig et al., 2018). Subsequently, research in medication adherence needs to change focus and continue to explore factors that are malleable and can be targeted in interventions to elicit meaningful changes in behaviour (Conn, Enriquez, et al., 2016).

Theory Use to Improve Medication Adherence

A promising avenue of research exploring the malleable factors of medication adherence may be through investigating psychological factors (Magura et al., 2014; Zeber et al., 2011). These factors are generally explored through the application of psychological theories of behaviour change, such as social cognitive theory (Bandura, 1986), the health belief model (Stretcher & Rosenstock, 1997), the transtheoretical model (Prochaska et al., 1992), information-behaviour-skills model (Fisher & Fisher, 1992), common-sense model (Diefenbach, 1996), adult learning theory (Knowles, 1978), the necessity-concerns framework (Horne & Weinman, 1999), and the theory of planned behaviour (Ajzen, 1991). These have all previously been explored in

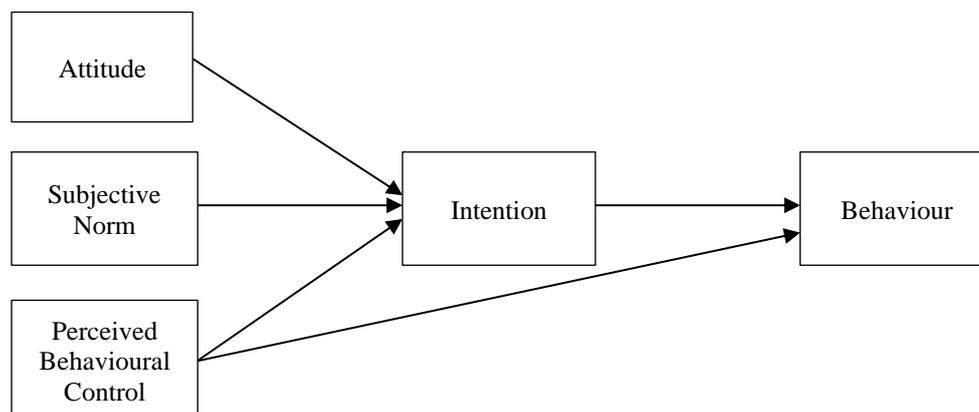
the context of medication adherence (Conn, Enriquez, et al., 2016). However, the findings and efficacy of these theories in predicting adherence is generally mixed and suggests that perhaps some of these theories are more suitable for other health behaviours, but not medication adherence (Noar & Zimmerman, 2005).

For example, social cognitive theory, which focuses on personal, behavioural and environmental factors, was identified as being only weakly predictive of medication adherence in a group of adults with depression (Bennett et al., 2018). A 2014 systematic review also identified that the utility of the health belief model, which is comprised of constructs such as perceived susceptibility, self-efficacy and perceived benefits and barriers, was poor, with the theory's constructs explaining little variance in medication adherence behaviours (Holmes et al., 2014). The necessities-concerns framework, which focusses on patients beliefs associated with their medication regimen, has often been successful in predicting adherence to medication regimens, or the lack thereof (Horne et al., 2007), but has been suggested to be equally as important in adherence when compared to other psychological predictors in other theories (Foot et al., 2016). Further, interventions based on these individual theories and their core constructs are not uncommon in the literature and have shown to vary greatly with regards to their specificity and feasibility in improving adherence (Molloy & O'Carroll, 2017). Subsequently, it has been suggested that perhaps combining such theories and applying these to medication adherence in attempts to predict more variance, may be beneficial (Conn, Enriquez, et al., 2016; Holmes et al., 2014; Rickles, 2010).

One theory that has often been combined with other theories, or individual constructs from other theories have been added to it, is the theory of planned behaviour (Ajzen, 1991). The theory of planned behaviour was created to improve the predictive ability of Fishbein and Ajzen's theory of reasoned action (Fishbein & Ajzen, 1975). The theory of planned behaviour (see Figure 1.1) is a two-stage model and proposes that three constructs directly predict an individual's intention to engage in a behaviour: attitudes, subjective norms and perceived behavioural control (Ajzen, 1991). The addition of perceived behavioural control, which is likened to that of self-efficacy, which is a concept from Bandura's (1986) social cognitive theory, was the only addition to the theory of reasoned action to create the theory of planned behaviour. Secondly, the theory posits that intention to engage in a behaviour is the strongest direct predictor of actual engagement in behaviour. Thirdly, since the addition of perceived behavioural control, the theory proposed that perceived behavioural control was not only a direct predictor of intention but also of engagement in behaviour (Ajzen, 1991).

Figure 1.1

The Theory of Planned Behaviour (Ajzen, 1991)



The original theory of planned behaviour theory has been applied to numerous behaviours, particularly health-related behaviours, and showed promise in its application across a range of different health behaviours (Armitage & Conner, 2001; Godin & Kok, 1996). A meta-analysis of the theories' predictive ability in health behaviours identified that it could predict approximately 44% of the variance in intention and 19% of the variance in behaviour (McEachan et al., 2011). The constructs of the theory have shown malleable qualities, such that behaviour change techniques used in interventions to manipulate the constructs to then elicit behaviour change, have shown success. A 2016 meta-analysis of interventions based on the theory of planned behaviour identified that overall, the behaviour change techniques used in interventions were successful in changing the constructs, albeit mostly moderate changes (Steinmetz et al., 2016). For example, interventions aimed at increasing skills for the behaviour found a significant moderate increase in positive attitudes for the behaviour and interventions that focussed on motivating participants identified significant increases in intention for the behaviour (Steinmetz et al., 2016).

However, the theory is not without its limitations. The most prominent issue with the theory, first identified in 1998 by Conner and Armitage, is the 'intention behaviour gap'. This 'gap' relates to the difficulty of predicting a substantial amount of the variance in behaviour with intention and perceived behavioural control (Sheeran, 2002), such that individuals may have high intention and perceived behavioural control but this is not always predictive of actual engagement (Sniehotta, Scholz, et al., 2005). Considering the theory's main contention is that intention is the strongest antecedent of behaviour, this

meant the theories' validity and feasibility in predicting behaviour was questioned (Sniehotta et al., 2014).

As the 'intention-behaviour gap' became more prominent across studies and reviews, attempts were made to strengthen its utility. The theory was either combined with other theories of behaviour change, such as self-determination theory (see Hagger & Chatzisarantis, 2009; Kor & Mullan, 2011), or it was extended upon by adding previously identified important constructs such as past behaviour (Norman et al., 2000), habit strength (Allom et al., 2016; de Bruijn, 2010), and executive function and self-regulation (de Bruin et al., 2012; Mullan et al., 2011; Wong & Mullan, 2009). The addition of these constructs strengthened the theory, for example, past behaviour alone accounted for 74.3% of the variance in breakfast consumption (Wong & Mullan, 2009). Despite this, calls were made by experts in the field to retire the theory and focus future research on applying more comprehensive theories to health behaviours (Sniehotta et al., 2014).

Specifically, with regards to adherence behaviours, a meta-analysis specific to adherence behaviours found that overall approximately 30% of the variance in intentions and only 9% of the variance in adherence were able to be predicted by the constructs of theory of planned behaviour in combination (Rich et al., 2015). These figures vary greatly to those of other behaviours. McEachan and colleagues' (2011) meta-analysis identified the theory was better able to predict other behaviours, such as physical activity, where 24% of the variance in behaviour was accounted for. In sun-protective behaviours, the theory has been found to predict approximately 25% of the variance in behaviour (Starfelt Sutton & White, 2016). Therefore, perhaps as suggested by

Noar and Zimmerman (2005) and McEachan and colleagues (2011), certain types of theories are better suited to being applied to certain behaviours because some theoretical constructs may not play a role in specific behaviours. For example, for behaviours that only require one step and have a distal benefit, such as vitamin use, the role of intention and habit appears to be equally important (Allom et al., 2018) meaning theories that are applied to this behaviour or similar ones, such as medication taking, should include both of these constructs. Furthermore, models such as the health belief model may be more appropriate for physical illness such as cardiovascular disease, as it includes constructs such as perceived susceptibility and severity of the threat of illness (Stretcher & Rosenstock, 1997).

In addition to taking into consideration the expert calls to apply different health psychology theories in research, perhaps exploring the applicability and predictive utility another more comprehensive theory of behaviour, that includes constructs that have previously been shown to be important in similar behaviours (e.g., vitamin use) in medication adherence will provide more insight into the possible malleable psychosocial factors of adherence.

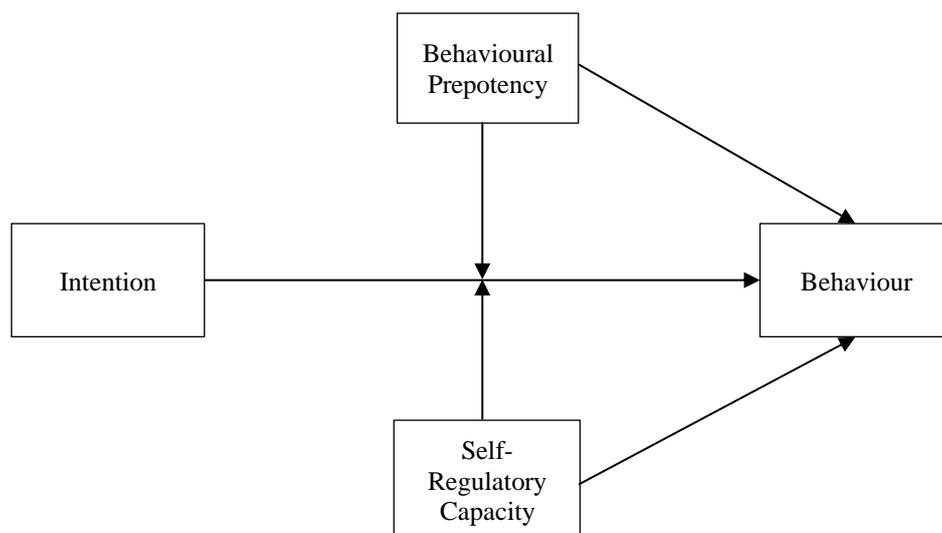
Temporal Self-Regulation Theory

One of these theories that takes into consideration the issues the theory of planned behaviour has had with the ‘intention-behaviour’ gap, is Temporal Self-Regulation Theory (Hall & Fong, 2007). According to the theory, engagement in behaviour is the result of various factors comprising mainly biological (e.g., self-regulatory and executive function capacity), and cognitive

(e.g., intention or motivation) factors. Temporal Self-Regulation Theory proposes dual processes, a rational or conscious process and an automatic or unconscious process, are responsible for performing a behaviour. It also proposes that these two processes not only work in conjunction with one another, but they are also separate processes that influence behaviour directly (see Figure 1.2). The theory first proposes that intention is the most proximal predictor of behaviour (Hall & Fong, 2007). Secondly, it proposes two constructs that directly predict behaviour: behavioural prepotency and self-regulatory capacity. Finally, it suggests that both behavioural prepotency and self-regulatory capacity can moderate the intention-behaviour relationship (Hall & Fong, 2007), such that behavioural prepotency or self-regulatory capacity strengthen the association between intention and behaviour.

Figure 1.2

Temporal Self-Regulation Theory (Hall & Fong, 2007)



Behavioural prepotency is considered to be the unconscious process in this model, such that it can be considered an automatic reflex or response (Barkley, 1997; Hall & Fong, 2007) to salient cues or past behaviour (Ouellette & Wood, 1998). Behavioural prepotency has often been defined by the combination of factors such as past behaviour, environmental cues, and habit strength. The stability of behaviour is not the result of only one of these factors, but rather a combination of them. Past behaviour is often regarded as one of the strongest predictors of future behaviour (Ajzen, 2011; Ouellette & Wood, 1998; Verplanken & Orbell, 2003). However, this is not surprising given that behaviours often become routinised and thus occur automatically (Ouellette & Wood, 1998). Studies show that the automatic nature of a behaviour, or the strength of the habit, increases the more the behaviour is repeated in a stable context and in response to salient environmental cues (Hall & Fong, 2007; Lally & Gardner, 2013; Neal et al., 2006; Ouellette & Wood, 1998). The theory proposes that both internal (e.g., biological drives) and external cues (e.g., visual or physical) play a role in the automatic execution of behaviour (Hall & Fong, 2007), such that when a cue is encountered, the behaviour is automatically elicited as a result of the behaviour being frequently repeated as a response to this cue. Over time, after repeated execution, the behaviour is now executed automatically with little conscious effort. As a result, an individual's motivation, or intention, to engage in the behaviour becomes less important in predicting the behaviour (Bargh, 1994; Hall & Fong, 2007; Lally & Gardner, 2013; Wood & Runger, 2016).

Previous research supports the pathways proposed by Temporal Self-Regulation Theory regarding the role of behavioural prepotency. For example,

a meta-analysis showed a medium-to-strong association between habit and physical activity and healthy eating behaviours and when habit was included as a moderator of the intention-behaviour relationship, the influence of intentions decreased as habit strength increased (Gardner et al., 2011). Similarly, another review of health behaviours has shown that when a behaviour is habitual the behaviour tends to persevere regardless of whether intention is high or not (Webb & Sheeran, 2006). Another study has also provided evidence for the role of cues in behaviour such that repeating a behaviour in response to a cue resulted in the behaviour becoming more habitual (Lally et al., 2010).

Self-regulatory capacity can be referred to as the rational or conscious process in Temporal Self-Regulation Theory. Unlike behavioural prepotency, self-regulatory capacity is said to be under volitional control such that an individual has the capacity to manage and control their thoughts, emotions and behaviours (Baumeister et al., 2007). Self-regulatory capacity includes cognitive processes such as self-regulation ability, self-control, planning, and executive functions (Booker & Mullan, 2013; Hall & Fong, 2007). Evidence supporting both the direct and moderating role of self-regulatory capacity in health behaviours has been shown in a study by Hall et al. (2008). This study showed that executive function predicted unique variance in both physical activity and dietary behaviours. Additionally, executive function also moderated the relationship between intention and engagement in these behaviours, such that, as executive function increased the role of intention in behaviour decreased (Hall et al., 2008). Similarly, the role of planning in moderating the intention-behaviour relationship is also well established such that individuals with greater planning ability experience more success in

translating their intentions into actual behaviour (Lally & Gardner, 2013; Michie et al., 2009; Schwarzer, 1992; Sniehotta, Schwarzer, et al., 2005).

Temporal Self-Regulation Theory was one of the theories suggested by Sniehotta et al. (2014) that should be applied to future health-behaviours instead of the theory of planned behaviour. With regards to medication adherence, Temporal Self-Regulation Theory and its hypotheses have yet to be applied. However, the theory provides promise in its applications as it has successfully been applied to other health behaviours such as healthy and unhealthy snacking (Evans et al., 2017), healthy lifestyle (Booker & Mullan, 2013), sugar-sweetened beverage consumption (Moran & Mullan, 2020), alcohol consumption (Black et al., 2017) and vitamin use (Allom et al., 2018). In these studies, between 18-55% of the variance in behaviour was accounted for by Temporal Self-Regulation Theory. Additionally, no intervention studies have been conducted that use Temporal Self-Regulation Theory as a theoretical basis, however, the individual constructs have. For example, Judah et al. (2013) provided participants who did not engage in teeth flossing with motivational information related to teeth flossing and instructed them to floss daily. It was found that 28 days post-intervention, participants that reported flossing more frequently also exhibited an increase in the automaticity (habit) for the behaviour, suggesting habit and automaticity are malleable constructs that can be targeted in interventions that then act as a mechanism of behaviour change. Similarly, in an intervention examining planning ability in sunscreen use, Zhou et al. (2015) asked participants to create two plans about their sunscreen use. The results identified significant improvements in both intention and planning ability in those that received the intervention compared to those

in the control group (Zhou et al., 2015). This change in planning also acted as a mediator for change in sunscreen use. This suggests that intention and planning are also malleable constructs and can be targeted and changed with the use of behaviour change techniques.

It is therefore proposed that Temporal Self-Regulation Theory and its constructs will also successfully be able to predict adherence to medication. The constructs of Temporal Self-Regulation Theory have been explored individually previously in reference to medication adherence and have shown to be important. For instance, habit strength has shown to be an important predictor in adherence to type 2 diabetes medication (Phillips et al., 2016) and prophylactic asthma medication (Bolman et al., 2011). Planning has also been shown to both directly predict adherence, as well as moderate the intention-adherence relationship in adherence to medications after coronary artery bypass surgery (Pakpour et al., 2014). Therefore, the application and exploration of Temporal Self-Regulation Theory, its constructs, and the proposed relationships between them in adherence to medication is an avenue that should be explored. Given its success in other behaviours and that adherence is still a global issue, Temporal Self-Regulation Theory may provide more in-depth information on which malleable psychological factors associated with adherence need to be targeted in interventions aimed at improving adherence globally.

Aims and Outline of the Thesis

The overarching objective of my thesis is to extend on previous research in adherence to medication by further exploring the role of malleable

psychosocial variables. Specifically, I first aim to test the utility of Temporal Self-Regulation Theory and its constructs in predicting medication adherence, and whether these constructs contribute to the prediction of behaviour over and above non-malleable factors such as side effects and medication regimen complexity (Chapters 2, 3 and 4). A second aim of this thesis is to see if improvements can be made to medication adherence using a simple intervention based on the findings of the above aim (Chapters 5 and 6). These two overarching objectives were addressed in five studies. In total, my thesis comprises seven chapters (including this introductory chapter), which are outlined below:

Chapter 2 presents the first study: *Can Temporal Self-Regulation Theory and its constructs predict medication adherence? A meta-analysis of the literature* (under review in Health Psychology Review) which addresses the overarching aim of the thesis by conducting a meta-analysis of the relationships between medication adherence and each of the constructs of Temporal Self-Regulation Theory. In this review, I aim to better understand the extent of the relationships between the Temporal Self-Regulation Theory constructs and medication adherence in previous literature, as well as the interactions between the constructs in medication adherence.

Chapter 3 comprises the second study: *Understanding the predictors of medication adherence: Applying Temporal Self-Regulation Theory* (published in July 2020 in Psychology and Health) which directly addresses the overarching aim of this thesis by applying Temporal Self-Regulation Theory over two-time points to assess the ability of the theory to predict adherence to medication. Previous research identified the importance of side effects and

medication regimen complexity (George et al., 2004; Osterberg & Blaschke, 2005) in medication adherence. Therefore, these two variables were examined and controlled for to ensure the true effects of psychological constructs of Temporal Self-Regulation Theory were identified.

Chapter 4 details the third study: *A qualitative application of Temporal Self-Regulation Theory to understand adherence to simple and complex medication regimens* (published in November 2020 in *Healthcare*). Within this study, I aimed to explore how the tenants of Temporal Self-Regulation Theory occurred in the everyday lives of individuals adhering to different medication regimens complexities. As the theory has only been applied once to medication adherence generally, in Chapter 3, and not to a specific medication regimen, it is unknown whether the same factors of Temporal Self-Regulation Theory are influential in adherence to both simple and complex medication regimens. Secondly, I wanted to investigate whether the findings from this study are similar to that identified in the quantitative study in Chapter 3 as well as to potentially identify any additional factors that the theory does not consider.

Chapter 5 includes the fourth study: *Adherence to the oral contraceptive pill: the roles of health literacy and knowledge* (published in December 2020 in *Health Psychology and Behavioral Medicine*). This chapter is the first chapter that focuses on the second objective, the intervention. The main aim of this chapter is to explore the variability in adherence to a simple medication regimen, which could be the focus of the intervention. Given the simplicity and commonality of taking the daily oral contraceptive pill, this seemed to be a good option. However, before confirming the suitability of this population and behaviour it was important to ensure there was enough

variability in adherence that warranted an intervention. Furthermore, within Chapter 4, I identified additional factors, not part of Temporal Self-Regulation Theory, that were deemed as being important in facilitating medication adherence. These two factors were health literacy and knowledge. These two factors are also malleable and may provide a deeper understanding of additional factors that are important in adherence. In this chapter, I explore the predictive ability of each factor, as well as their interaction with adherence to a simple medication regimen, while assessing the variability in adherence to the daily oral contraceptive pill.

Chapter 6 presents the fifth study: *A simple intervention using cues and knowledge to improve adherence for taking the oral contraceptive pill in Australian females*. Within the previous chapters, I identified the overarching importance of cues (Chapter 3 and Chapter 4) and knowledge (Chapter 4 and Chapter 5) in medication adherence. In this final study, I conduct a simple intervention to investigate the influence of both cues and knowledge on not only improving medication adherence but also increasing habit strength for taking the oral contraceptive pill. The oral contraceptive pill was chosen as the population to ensure consistency with previous chapters and because this regimen is considered simple and thus a good starting point to understand the intervention's efficacy.

Chapter 7 concludes the thesis with a general discussion of the findings of the thesis, implications for theory, research, limitations, and future research, and finishing with an overall conclusion.

**Chapter 2: Can Temporal Self-Regulation Theory and Its Constructs
Predict Medication Adherence? A Meta-Analysis of the Literature**

Introduction to Chapter 2

In this first study, I explore the predictive utility of applying the constructs of Temporal Self-Regulation Theory to medication adherence by reviewing the literature on intention, behavioural prepotency, self-regulatory capacity, and medication adherence. Specifically, I synthesise and statistically meta-analyse the associations between these constructs and medication adherence to assess and evaluate the current strength of the evidence.

Under Review:

Liddelow, C., Mullan, B., & Boyes, M. (Under Review). Can Temporal Self-Regulation Theory and Its Constructs Predict Medication Adherence? A Meta-Analysis of the Literature. *Health Psychology Review*

Author	Contribution	I acknowledge that these represent my contribution to the above research output Signed:
Caitlin Liddelow	Development of research question, data collection, data management, data analysis, interpretation of results and discussion, manuscript preparation, reviewing and editing of drafts	
Barbara Mullan	Assisted with development of research question, interpretation of results, and manuscript preparation, reviewing and editing of drafts	
Mark Boyes	Assisted with development of research question, interpretation of results, and manuscript preparation, reviewing and editing of drafts	

Abstract

Rates of adherence to prescription medication are low and the previous application of psychosocial models to predict medication adherence has resulted in mixed findings. However, a more recent model of behaviour, Temporal Self-Regulation Theory, shows promise in predicting medication adherence. However, the relationships between its three main constructs (intention, behavioural prepotency, and self-regulatory capacity) and medication adherence should be established to ensure applying the theory is worthwhile. This study aimed to conduct three individual meta-analyses to evaluate the predictive ability and importance of the constructs of Temporal Self-Regulation Theory in medication adherence. A search of five electronic databases identified a total of 69 studies that measured and reported a correlation between one or more of the constructs and medication adherence. Only one study measured all three constructs of the theory, and six studies measured two. The remaining 62 studies measured only one individual construct. A random-effects meta-analysis was conducted for each construct and identified weak-to-moderate positive associations between intention ($k = 33$; $r = .302$, 95% CI = 0.220, 0.385), behavioural prepotency ($k = 14$; $r = .282$, 95% CI = 0.175, 0.388), self-regulatory capacity ($k = 30$; $r = .137$, 95% CI = 0.069, 0.205) and medication adherence. There was also no evidence of publication bias in any of the analyses. Associations were invariant across illness type (acute vs. chronic) and study design (cross-sectional vs. longitudinal). There was high heterogeneity within each analysis (I^2 ranging 87.82 to 97.75), specifically in the measurement of adherence, making quantitative synthesis difficult. None of the studies included in the analysis

explored the interactions between any of the Temporal Self-Regulation Theory variables. Future research should consider applying the theory to medication adherence to assess the relationships between the variables. We also call for action regarding the use of similar measures of medication adherence to ensure greater ease of synthesis of findings in the future.

Introduction

When medication regimens are adhered to, individuals are three times more likely to experience positive health outcomes compared to those who do not adhere correctly (DiMatteo et al., 2002). Similarly, adherence to prescription medication is associated with better recovery or management of the disease; a decrease in the presence of comorbid conditions; a decrease in the likelihood of experiencing adverse events; decreased risk of mortality; and a reduction in the total amount of money spent on health care (Chisholm-Burns & Spivey, 2012). Yet, despite this, medication adherence remains a global health concern with an estimated 50% of people with a chronic disease, who live in high-income countries, do not adhere to their medication regimen (Brown & Bussell, 2011; Clyne et al., 2016; De Geest & Sabaté, 2003), with even lower rates estimated for those with acute conditions (Haynes et al., 2002). It is estimated that approximately 4% of all hospital admissions in North America, Europe, Asia and Australia are the direct result of non-adherence to prescription medications (Mongkhon et al., 2018). As the population continues to age, it is likely that non-adherence to prescription medication will worsen, globally, as more people will be required to take more medications to treat the rising multimorbidity of disease (Gurwitz et al., 2003; Ho et al., 2009).

One of the first steps to improving medication adherence and reducing the rates of non-adherence is to facilitate changes in behaviour (Kleinsinger, 2018). The application of psychosocial models of behaviour to medication adherence has been one way in which attempts have been made to further understand adherence with the hopes of changing behaviour (see Lin et al., 2016; Phillips et al., 2013; Williams et al., 2009; Yue et al., 2015). However,

these theories and the interventions based on them have reported differing findings and effects (Conn, Ruppap, et al., 2016; Conn & Ruppap, 2017). One of the most commonly applied and extended models of behaviour is the theory of planned behaviour (Ajzen, 1991), especially in the context of adherence behaviours (Bane et al., 2006; Kopelowicz et al., 2015; McKinney et al., 2015). The theory of planned behaviour posits that behavioural intention is the most pertinent predictor of behaviour, and that perceived behavioural control also directly predicts both intention and behaviour (Ajzen, 1991). However, the greatest criticism and discrepancy of the theory is its issues in actually predicting behaviour, which is commonly referred to as the 'intention-behaviour gap' (Armitage & Conner, 2001; Sheeran & Webb, 2016), and suggests that intention alone is a poor predictor of health behaviour. A 2015 meta-analysis by Rich et al. (2015) found that the theory of planned behaviour variables (intention and perceived behavioural control) were only capable of predicting approximately 9% of the variance in adherence behaviours. In attempts to negate the lack of predictive ability of the theory of planned behaviour, many psychosocial variables have been added to the model to explore their potential in accounting for additional variance (e.g., de Bruin et al., 2012; Rhodes & Dickau, 2012). Psychosocial variables such as habit strength, anticipated regret and self-regulatory variables like planning have all been shown to predict behaviour over and above the theory of planned behaviour variables (Conner & Armitage, 1998; Gardner et al., 2011; Sniehotta et al., 2014). While the addition of such variables adds to the models' predictive ability, many researchers were still concerned with the validity and

utility of the theory and called for its retirement in health behaviour research and to instead focus on other theories of behaviour (Sniehotta et al., 2014).

A more recent theory of behaviour that is beginning to be applied to health behaviours is Temporal Self-Regulation Theory (Hall & Fong, 2007). Temporal Self-Regulation Theory is a dual-process model that follows on from the theory of planned behaviour, and while still suggesting that intention is the most proximal predictor of behaviour, it includes both behavioural prepotency (the frequency and habitual/automatic of the behaviour) and self-regulatory capacity (the ability to regulate emotions, thoughts and behaviours) as direct predictors of behaviour but also as individual moderators of the intention-behaviour relationship (Hall & Fong, 2007). Behavioural prepotency is the automatic component of the theory that occurs with little thought and is typically measured by habit strength, the use of cues and the frequency of past behaviour. Self-regulatory capacity is the rational component of the theory, requiring conscious thought and effort and is typically measured by executive function ability, self-regulation skills and planning ability (Hall & Fong, 2007). As the theory is fairly new (compared to many other theories), its applicability to various behaviours is limited. However, it has been used to predict volunteering behaviour (Mullan et al., in press), healthy and unhealthy snacking (Elliston et al., 2017; Evans et al., 2017), binge drinking and alcohol consumption (Black et al., 2017; Murray & Mullan, 2019), sugar-sweetened beverage consumption (Moran & Mullan, 2020), vitamin and supplement use (Allom et al., 2018), and healthy lifestyle behaviours (Booker & Mullan, 2013).

Although the theory has yet to be applied to medication adherence, the specific components of Temporal Self-Regulation Theory (intention, behavioural prepotency, and self-regulatory capacity) have been used with mixed findings. Some studies show habit strength is associated with better medication adherence (Phillips et al., 2016) whereas others show that habit strength is not associated with medication adherence (Liddelow, Mullan, & Novoradovskaya, 2020). Therefore, the purpose of this meta-analysis is to synthesise the literature, and independently assess the relationships between each of the constructs of Temporal Self-Regulation Theory and medication adherence. The results of this meta-analysis will not only highlight the strength of associations between the constructs and medication adherence but will also provide targets for interventions aimed at improving medication adherence.

It will also assess the moderating impacts of illness/medication type, regimen complexity, as well as methodological factors such as study design and the type of measure of adherence. Medication adherence varies depending on the illness (DiMatteo, 2004) and therefore the possible influence of this on the relationship between the Temporal Self-Regulation Theory constructs and adherence will be explored. Similarly, more complex medication regimens are also associated with higher levels of non-adherence (George et al., 2004; Stone et al., 2001). Regarding study design, the relationship between two constructs may be different when measured at the same time point compared to if they are measured weeks or months apart. When measuring behaviour cross-sectionally, past or current behaviour rather than future behaviour is being measured and therefore may not be accurately representing the strength of the relationship (McEachan et al., 2011; Weinstein, 2007). As adherence is a long-

term behaviour there may be differences in the strength of relationships over time (Rich et al., 2015). Furthermore, measurement in medication adherence has long been an issue (Brown & Bussell, 2011; Lam & Fresco, 2015). Self-report measures of adherence tend to be subject to social desirability bias and over-estimating of adherence, as well as not always measuring behaviour but rather measuring attitudes, beliefs or barriers towards medication adherence (Nguyen et al., 2014). While objective measures of adherence such as Medication Event Monitoring Systems (MEMS[®]) and prescription refills are also limited in that they do not necessarily measure adherence but rather opening a medication bottle or refilling a prescription. Therefore, the way adherence was measured will be a moderator to not only assess its possible influence on the relationships but also to see which measures of adherence are the most commonly used.

Aim and Hypotheses

The current meta-analysis aims to conduct three individual analyses to identify and evaluate the predictive ability and importance of the constructs (intention, behavioural prepotency, and self-regulatory capacity) of Temporal Self-Regulation Theory in medication adherence behaviours. A secondary aim of this meta-analysis, following the moderation hypotheses of Temporal Self-Regulation Theory, was to explore the strength of the interactions between the Temporal Self-Regulation Theory constructs, as well as their individual effect, on medication adherence. It was hypothesised that all three Temporal Self-Regulation Theory constructs would be significantly positively associated with medication adherence, such that greater intention, higher habit strength, greater use of cues, higher frequency of past behaviour, better executive function,

planning, self-control, and self-regulation would be associated with better medication adherence. Secondly, it was hypothesised that as per the theory, behavioural prepotency and self-regulatory capacity would moderate the intention-adherence relationship such that the relationship between intention and adherence would strengthen as self-regulatory capacity strengthens, but the relationship would weaken as behavioural prepotency increases. Thirdly, it was hypothesised that the strength of the relationships would be different depending on the illness of interest, such that illnesses that are more severe or chronic will have worse adherence (DiMatteo, 2004). Fourthly, based on previous research (George et al., 2004) medication regimen complexity will moderate the relationships such that samples with a more complex medication regimen will have weaker associations between adherence and intention, behavioural prepotency, and self-regulatory capacity. The study design (cross-sectional or longitudinal) is hypothesised to moderate the associations between the Temporal Self-Regulation Theory constructs and adherence, such that studies using longitudinal designs will show weaker associations compared to studies with cross-sectional designs. Finally, with previous research highlighting the stronger relationship between self-report subjective measures and medication adherence (Nguyen et al., 2014), it was hypothesised that studies measuring adherence with subjective measures would have stronger associations between the Temporal Self-Regulation Theory constructs and medication adherence.

Methods

A protocol for this review was pre-registered with Prospero (CRD42019141395) prior to the commencement of the search for studies. Changes to the protocol are minimal, but where changes have been made, these have been reported. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were also followed (Liberati et al., 2009) and a checklist is included in Appendix B. All data associated with this review is also accessible on Open Science Framework (<https://osf.io/w9ktx>).

Search Strategy

Electronic searches of the databases PsychINFO (1806-present), Medline (1950-present), EMBASE (1974-present), CINAHL (1900-present) and Web of Science (1900-present) were conducted in November 2019. After consulting with the University librarian, some small changes were made to the search strategy presented in the registered protocol. The databases, PubMed and Scopus were removed and Medline, EMBASE and CINAHL were added as they are all focussed in different research areas. The keywords and inclusion criteria in the protocol did not change, however the search strategy was separated into three individual searches (based on the temporal self-regulation theory construct) in each database, to ensure no possible studies were missed if the search was conducted all in one. All variables of interest were searched in separate searches in each database. An example search strategy for each variable of interest can be seen in Table 2.1. No search limits, such as language or year of publication, were applied. A combination of text words and subject headings (e.g., MeSH terms) were used in the search strategy, with slight variations between databases. The use of truncation, phrases and wildcards was

also used. An individual literature search in each database was conducted for each of the three predictors of interest (intention, habit, and self-regulation) to ensure no key articles were missed. Some of the text words used in the searches included: (intent* OR intention*), (habit* OR cue* OR automatic*), (self-regulat* OR “executive function” OR self-control) AND (medication OR medicine OR “drug therapy” OR pharmacotherapy*) AND (adhere* OR comply OR compliance OR non-adherence or nonadherence).

Eligibility Criteria

Studies were eligible for inclusion in the review if they investigated the role, influence, or predictive ability of at least one of the constructs of interest (intention, habit, cues, past behaviour, executive function, self-regulation, self-control, or planning) in medication adherence, with medication adherence the outcome measure. All measures of adherence (e.g., self-report, electronic monitoring, and biological markers) were eligible for inclusion. Studies that (i) measured adherence to medical or psychological therapy, lifestyle, or addiction treatment, given these are not medication related (ii) involved animals, (iii) a sample population below 18 years of age and, (iv) not containing quantitative data, were excluded.

Table 2.1

Example Search Strategy for ‘Intention’ From PsychINFO (Ovid)

-
1. exp Intention/ or exp Behavioral Intention/
 2. Drug Therapy/
 3. exp Treatment Compliance/
 4. (intent* or intention*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
 5. (medication* or medicine* or drug therapy or pharmacotherap*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
 6. (adhere* or comply* or compliance or non-adherence or nonadherence).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
 7. 1 or 4
 8. 2 or 5
 9. 3 or 6
 10. 7 and 8 and 9
-

Study Selection Process

Upon completion of the database searches, all articles were downloaded into Endnote. Here, duplicates were identified and removed. Title and abstract screening were conducted simultaneously to identify eligible studies meeting the inclusion criteria. The primary reviewer screened 100% of the titles and abstracts, with a secondary reviewer screening a random 20% of the articles to ensure agreement and consistency. Following the title and abstract screening, the full texts of each article were sourced and reviewed by the primary reviewer. Reasons for exclusion of articles at this stage included: being a duplicate of an already included study, adherence to health-related behaviours rather than medication, no measures of variables of interest, wrong population, a protocol for an RCT, treatment of addiction, not original research, not in English-language, unable to locate the full-text, adherence not being the

outcome variable, and participants having a cognitive impairment (particularly in studies related to self-regulation or executive function). Some of the studies included in the full-text stage were conference abstracts and if author details were available, they were contacted to request the full-text associated with this abstract. Similarly, for articles with statistics unsuitable for the analysis or no correlation matrix, the corresponding author was contacted via email requesting additional information. If there was no response from authors, the article was subsequently removed from the analysis.

Data Extraction

The primary reviewer independently extracted the key data items from the included articles using a data extraction form in Excel, created for this review. Several study characteristics were extracted including publication details, sample demographics, study design, illness or medication of interest, the Temporal Self-Regulation Theory construct of interest that was measured, types of measures used, outcome measure/s of adherence and relevant statistical results.

Analytic Strategy

Zero-order correlation coefficients were the chosen effect size for this meta-analysis due to the expectation that other correlational effect size indicators will control for different covariates, which may obscure the true relationship between Temporal Self-Regulation Theory constructs and adherence. Similarly, it was deemed the most appropriate as many of the studies employed cross-sectional correlational research designs. If authors included statistics such as β (beta) or adjusted Odds Ratios (OR), they were computed or transformed to correlation coefficients using the online effect-size

calculator by Lenhard and Lenhard (2016)

(https://www.psychometrica.de/effect_size.html). The standard error of each correlation co-efficient was manually calculated using the formula:

$$SE = (1-r^2)/\sqrt{N}$$

With studies that used more than one measure of medication adherence, the correlation coefficient was extracted for both measures. This was done to ensure subjective and objective measures were both represented in the analysis and their effects were not conflated with one another. If different samples were reported in the same study (e.g., older adults and younger adults), with different results, both samples were retained for analysis.

All meta-analytic results were calculated using Hedges random-effects model in JASP v0.12.0.0 (JASP Team, 2020). In the protocol, Comprehensive Meta-Analysis (CMA) software was proposed. However, more recently JASP, a freely available software with meta-analytic options, which are similar to those offered by CMA, has become popular and thus the collective decision was made to use JASP instead of CMA. The proposed statistical analyses did not change. A random-effects model was chosen as it assumes that effect sizes are different between studies (heterogeneity), and we expected this as the studies included were not all exploring a specific illness or medication. In addition, a random-effects model also calculates the most precise estimation of the pooled effect size when there is heterogeneity between studies (Field, 2001). To assess the degree of heterogeneity, Q and I^2 statistics were used, with I^2 indicating the proportion of variance attributable to heterogeneity between studies. According to Higgins et al. (2003), I^2 statistics of 25%, 50% and 75% are considered low, moderate and high values of heterogeneity, respectively.

To examine the effect of individual moderators on the association between the predictor variable and medication adherence, univariate meta-regressions were conducted. Type of illness of interest (e.g., cardiovascular, HIV) was originally proposed as a moderator, however due to low numbers of studies for specific illness groups they which were subsequently collapsed into broader categories (acute, chronic), study design (e.g., cross-sectional, longitudinal), and the type of measurement of adherence (e.g., subjective, objective or composite) were tested as moderators in each individual meta-analysis. Type of measure of adherence was originally proposed to be grouped according to self-report, electronic, objective, bodily indicators, chemical, however similar to above, some categories comprised of a too small number of studies and thus the categories were broadened. Study design was not originally proposed as a moderator, however as the theory is designed as a prospective theory of behaviour the collective decision was made during data extraction to include this as a moderator as relationships over time can vary from relationships cross-sectionally (Rich et al., 2015). As side-effects associated with the medications or illnesses and the regimen of the sample were rarely reported in studies, these moderation analyses could not be conducted as per the protocol. The possibility of publication bias was tested using Egger's test, which if significant at $p < .05$, indicates that publication bias is considered influential (Egger et al., 1997). A fail-safe n test was originally proposed, but with the change of software Egger's test was the best alternative.

Moderator Coding

To assess the potential moderating impact of illness type, illnesses of similarity were planned to be grouped together. However, large heterogeneity

was identified in the included studies, and it was decided that this was not plausible. Thus, illness type was coded according to whether it was 1 = acute/short term or whether it was 2 = chronic/long-term. Acute illnesses were defined as those only requiring a short-term prescription (e.g., antibiotics) or those that were when needed such as prophylactic asthma inhalers. Chronic illnesses were defined as those that require continued and long-term use of medication. Studies that did not focus on a specific illness, and included various ones, were unable to be coded. The possible moderating effect of medication regimen complexity could not be tested as too few studies reported this information. Studies were also classified according to their study design, either 1 = cross-sectional or 2 = longitudinal. Furthermore, studies were coded into three groups based on the type of medication adherence measure used: 1 = subjective, 2 = objective and 3 = composite of both. Due to aforementioned measurement issues in medication adherence, to identify the different types of subjective measures that are used to measure medication adherence, all studies were further coded into five groups: 1 = measures behaviour, 2 = measures attitudes/beliefs, 3 = objective measure, 4 = composite of both, 5 = items made for study.

Results

Study Selection

From the electronic database searches, a total of $k = 15,697$ published and unpublished studies were identified across all three variables of interest. After duplicates were removed ($k = 5,169$) a total of $k = 10,528$ studies remained for screening. Title and abstract screening were conducted simultaneously for each variable of interest and $k = 10,236$ studies were

excluded. The remaining 293 studies ($k = 128$ in intention, $k = 74$ in behavioural pre-potency, and $k = 91$ in self-regulatory capacity) were subjected to full-text screening. Of these, $k = 27$ remained in intention, $k = 14$ remained in behavioural prepotency and $k = 29$ remained in self-regulatory capacity. Reasons for exclusion during full-text screening included duplicates or using the same dataset, the wrong sample (e.g., adolescents), medication adherence not the outcome, and not original research (e.g., discussion pieces). Seven studies (Banas et al., 2017; Cook et al., 2015; de Bruin et al., 2012; Guénette et al., 2016; Hoo et al., 2017, 2019; McCloskey & Johnson, 2019) were identified as measuring more than one variable of interest and thus these studies were included in each of the analyses. A total of $k = 33$ studies were included in the intention quantitative synthesis, $k = 14$ in the behavioural prepotency quantitative synthesis and $k = 30$ in the self-regulatory capacity quantitative synthesis. Overall, $k = 69$ studies with 72 samples were included. There was an agreement rate of 92.7% (Cohens $\kappa = 0.55$) between the two reviewers with regards to the studies that should be included in the review at the title and abstract screening stage. See Figure 2.1 which summarises the identification, screening, eligibility, and inclusion procedures. See Table 2.2 for a summary of the studies included in each meta-analysis.

Description of Studies, Samples and Measures of Medication Adherence

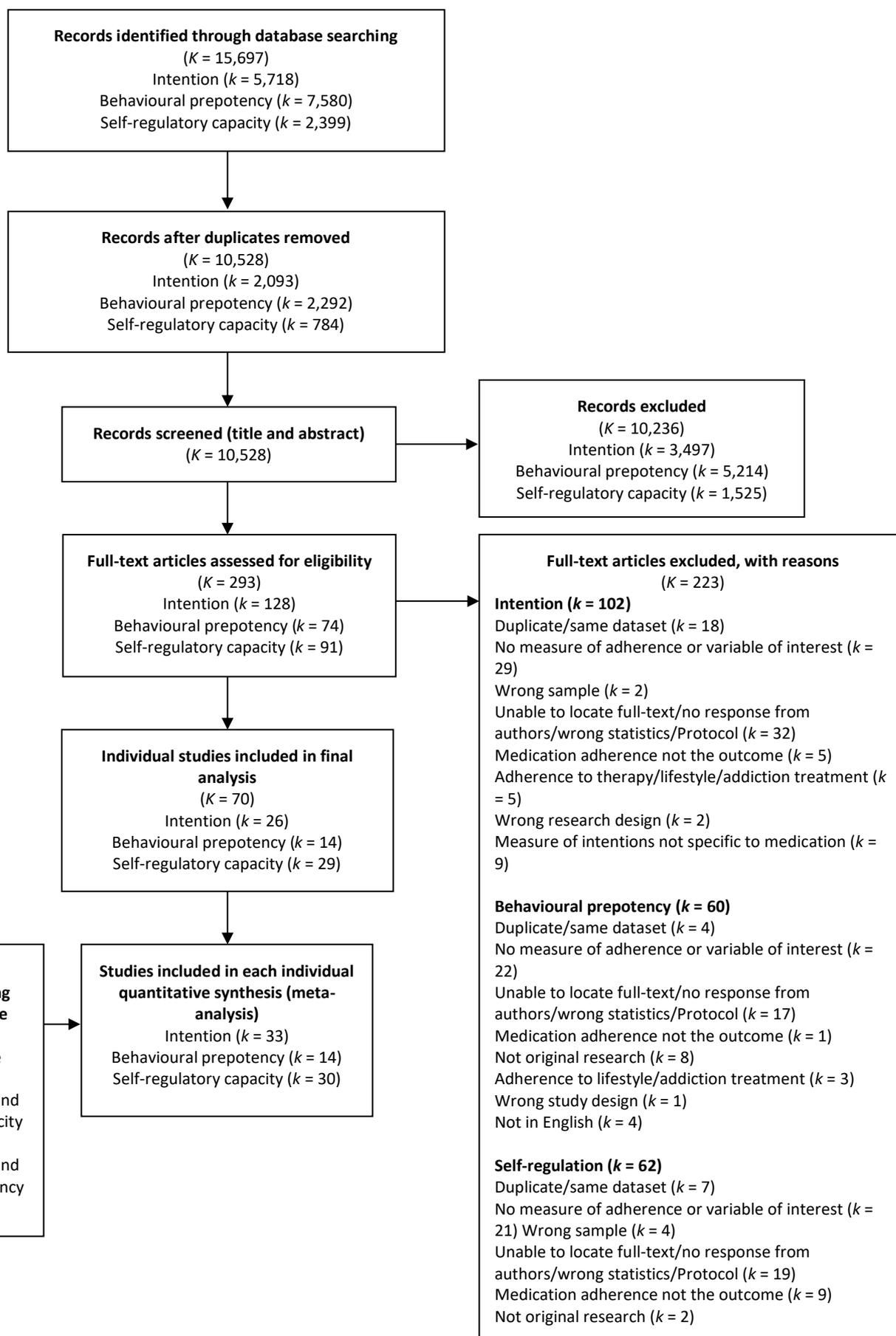
Studies were conducted between 1988 and 2019, with $k = 60$ published and $k = 9$ unpublished. The year 2012 had the most included studies ($k = 7$), followed by 2016 and 2017 with $k = 6$ studies each. Across the 72 samples, sample size ranged from 16 participants (Insel et al., 2008) to 1,433 participants (Molfenter et al., 2012), with a mean sample size of 235.32 ($SD =$

251.28). The mean age across all samples was 53.89 years ($SD = 13.45$), ranging from 20 years of age (Molloy et al., 2012) to 78 years (Insel et al., 2006; Stoehr et al., 2008). Females made up on average 49.60% of samples. Most of the studies ($k = 40$) contained samples from the Americas, followed by Europe ($k = 15$). Regarding research design, $k = 38$ studies used cross-sectional designs and $k = 31$ used prospective or longitudinal designs with follow-up's ranging from one week to two years. Human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) was the most common illness of focus ($k = 15$), followed by cardiovascular diseases ($k = 13$).

Subjective (self-report) measures of medication adherence used in $k = 57$ studies ($k = 50$ only used a subjective measure), $k = 29$ studies used objective measures ($k = 22$ only used objective measures) and $k = 3$ used a composite measure. The most commonly used subjective measure of medication adherence was the Medication Adherence Report Scale (Horne & Weinman, 1999) which was used in $k = 9$ studies. However, the most commonly used measure of medication adherence overall was Medication Event Monitoring Caps (MEMS[®]), which was used in $k = 18$ studies. Other commonly used measures of adherence included the Morisky Medication Adherence Scale (MMAS-8[®]; Morisky et al., 2008), pharmacy refill records, and specific questions made for the study.

Figure 2.1

PRISMA Diagram Summarising the Flow of Studies



Intention Meta-Analysis

A total of $k = 33$ studies that included a measure of intention were included in the meta-analysis. Three studies included more than one measure of medication adherence. The test of residual heterogeneity was significant $Q(36) = 1064.73, p < .001, I^2 = 95.90$. The random-effects meta-analysis identified a significant association between intention to adhere and medication adherence (Pooled $r = 0.302$, 95% CI = 0.220, 0.385, $p < .001$). See Figure 2.2 for the forest plot of this association. Egger's test of publication bias was non-significant ($p = .065$) meaning publication bias was not influential. See Figure 2.3 for the funnel plot.

Behavioural Prepotency Meta-Analysis

A total of $k = 14$ studies that measured habit strength ($k = 12$) or cues ($k = 2$) were included in the meta-analysis. Four studies included more than one measure of medication adherence. The test of residual heterogeneity was significant $Q(22) = 794.96, p < .001, I^2 = 97.75$. The random-effects meta-analysis revealed a significant association between habit strength and medication adherence (Pooled $r = 0.282$, 95% CI = 0.175, 0.388, $p < .001$). See figure 2.4 for the forest plot visualising the association. Egger's test of publication bias was non-significant ($p = .453$), meaning it is not influential. See Figure 2.5 for the funnel plot.

Self-Regulatory Capacity Meta-Analysis

A total of $k = 30$ studies with 33 different samples that measured self-regulation ($k = 3$), self-control ($k = 2$) or executive function ($k = 25$), were included in the meta-analysis. Two studies had more than one sample and nine studies used more than one measure, particularly when measuring executive

function. The test of residual heterogeneity was significant $Q(45) = 391.50, p < .001, I^2 = 87.82$. A random-effects meta-analysis revealed a significant association between self-regulatory capacity and medication adherence (Pooled $r = 0.137, 95\% \text{ CI} = 0.069, 0.205, p < .001$). See figure 2.6 for the forest plot showing this association. Egger's test of publication bias was non-significant ($p = .342$) meaning publication status was not influential. See Figure 2.7 for the funnel plot.

Moderator Analysis

Illness type, study design, and type of medication adherence measure were all tested as moderators of the association in each analysis. In the behavioural prepotency and self-regulatory capacity meta-analyses, more than one variable of the construct was measured (e.g., habit or cues as a measure of behavioural prepotency and self-regulation or executive function as a measure of self-regulatory capacity) and therefore the specific variable measured in the study was also examined as a potential moderator of that specific association. The analysis showed the type of illness, whether it was acute or chronic, did not moderate the association between any of the three Temporal Self-Regulation Theory constructs and medication adherence. The study design also did not moderate either of the three associations. Type of medication adherence measure only moderated the association between self-regulatory capacity and medication adherence, such that the use of a composite measure adherence had a significantly stronger association with self-regulatory capacity ($B = 0.30, p = .024$) compared to only using a subjective or an objective measure. The possible moderating role of the different types of subjective measures used (e.g., behaviour or attitudes/beliefs) was tested and showed that different

subjective measures of adherence did not moderate the intention or self-regulatory capacity associations with adherence, but did significantly moderate the behavioural prepotency association with adherence such that using an attitudes or beliefs-like measure of adherence (e.g., MARS-10, Adherence Attitude Inventory) had a significantly weaker association ($B = -0.66, p < .001$) with behavioural prepotency compared to a behaviour-like measure of adherence (e.g., MARS-5, MMAS-8). However, in this group of studies, only one study ($N = 201$; Cook et al., 2015) used an attitudes/beliefs measure of adherence. In the behavioural prepotency analysis, the variable measured (habit strength or cues to action) significantly moderated the association, such that habit strength ($B = 0.42, p < .001$) had a significantly stronger association with adherence compared to cues to action. However, only two studies measured cues to action ($N = 801$; Cook et al., 2015; Widjanarko et al., 2018). In the self-regulatory capacity analysis, the measurement of different variables (executive function, fluid ability, total cognitive functioning, self-regulation, and self-control) did not moderate the association. See Table 2.3 for all the moderation analyses.

Systematic Review of Temporal Self-Regulation Theory Relationships

In line with Temporal Self-Regulation Theory, which proposes both behavioural prepotency and self-regulatory capacity moderate the relationship between intention and behaviour, the studies that measured one or more of the Temporal Self-Regulation Theory constructs was further examined. Of the 69 total studies included across the three meta-analyses, only one study by Hoo et al. (2017) measured all three constructs of Temporal Self-Regulation Theory. However, the study did not apply the theory, but rather explored the predictive

ability of each construct independently. Two additional studies (Banas et al., 2017; de Bruin et al., 2012) included measures of intention and self-regulatory capacity, and four studies included measures of intention and behavioural prepotency (Cook et al., 2015; Guénette et al., 2016; Hoo et al., 2019; McCloskey & Johnson, 2019). These six studies also did not test or report any interactions between the variables of interest.

Risk of Bias Methods

The study quality and risk of bias of each study was assessed using the National Heart, Lung, and Blood Institute (NHLBI) Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies. This tool provides 14 areas of quality that a study can be assessed on. Overall, $k = 15$ out of 71 (21.13%) studies assessed were deemed to be ‘poor quality’ or ‘high risk of bias’ (Belaiche et al., 2017; Ben-Natan & Noselozich, 2011; Cochran & Gitlin, 1988; Fai et al., 2017; Farmer et al., 2006; Hagger et al., 2016; Ho & Lee, 2014; Ikechuwku et al., 2010; Jessop & Rutter, 2003; McCloskey & Johnson, 2019; Moore, 1995; Stilley et al., 2010; Stoehr et al., 2008; Waldrop-Valverde et al., 2006; Widjanarko et al., 2018), $k = 28$ out of 71 (39.44%) were identified as being of ‘fair quality’ and the remaining $k = 27$ out of 71 (38.02%) were deemed to be of ‘good quality’. The poor-quality ratings were mainly the result of having a cross-sectional design which limits the understanding of the predictive ability of the variables in adherence, not justifying the sample size or providing a description of power and not providing specific details about the sample. No studies were deemed too poor quality to warrant exclusion from the analysis. See Table 2.4 for a summary of whether each study included in analysis met quality criteria and risk of bias safeguards.

Table 2.2*Summary of Studies Included in The Meta-Analysis*

Author and year	Country	Illness of interest	Total N	Mean age years (SD) of sample	% of sample male	Study design	Length of follow-up	Measure of variable	Measure of medication adherence		Results
									Type of measure	Name	
Intention Meta-Analysis											
Banas et al. (2017)	Tanzania	HIV /AIDS	158	43.75 (10.5)	30.7	L	5 months	Self-report 3 items made for study	O	Medication event monitoring system (MEMS®)	Intention was weakly negatively associated with adherence at 5 months ($r = -0.07$)
Belaiche et al. (2018)	France	Kidney transplant	408	54	61.2	C	N/A	-	S	Compliance Evaluation Test (CET)	Intention was moderately negatively associated with adherence ($r = -0.307$)
Ben-Natan & Noselozich (2011)	Israel	Various	250	-	47.0	C	N/A	Self-report 3 items made for study	S	6 items made for study	Intention was moderately positively associated with adherence ($r = 0.25, p < .001$)
Chisholm et al. (2007)	USA	Renal transplant	158	51.0 (12.4)	60.1	C	N/A	Self-report 2 items made for study	O	Pharmacy refill data	Intention was moderately positively associated with adherence ($r = 0.46, p < .01$)
Cochran & Gitlin (1988)	USA	Bipolar Disorder	48	40.0	35.4	C	N/A	Self-report 1 item made for study	S	5 items adapted from Cochran (1984)	Intention was strongly positively associated with adherence ($r = 0.88, p < .001$)
Conner et al. (1998) (A and B)	England	Schizophrenia, depression, personality disorders or psychosis	61	-	-	L	9 weeks	Self-report 5 items made for study	S	1. Self-report by patient - % of time compliant 2. Self-report by clinician - % of time compliant	Intention was moderately positively associated with adherence ($r = 0.56, p < .01$) and clinician self-

											report adherence ($r = 0.43$, $p < .01$)
Cook et al. (2015) (A and B)	USA	Glaucoma	201	65.0 (11.2)	27.69	L	2 months	Intention subscale from the Adherence Attitude Inventory	O S	1. MEMS® 2. Adherence Attitude Inventory (6 days retrospective)	Intention was weakly positively associated with MEMS adherence ($r = 0.27$) and subjective adherence ($r = 0.32$)
de Bruin et al. (2012)	The Netherlands	HIV	56	48.9 (9.1)	88.0	L	3 months	Self-report 2 items made for study	CO	MEMS® and 1 self-report item	Intention was moderately positively associated with adherence ($r = 0.55$, $p < .001$)
Fai et al. (2017)	USA	Type 2 Diabetes	115	50.97	-	C	N/A	-	S	Morisky Medication Adherence Scale (MMAS-8®)	Intention was weakly positively associated with adherence ($r = 0.29$, $p < .01$)
Farmer et al. (2006)	England	Type 2 Diabetes	121	66.0	52.1	C	N/A	Self-report 2 items made for study	S	Medication Adherence Report Scale (MARS) – 5 items	Intention was weakly positively associated with adherence ($r = 0.29$, $p < .01$)
Fransen et al. (2009)	The Netherlands	Dyspepsia (indigestion)	347	54.0 (14.00)	58.0	L	-	Self-report 2 items made for study	S	Asthma Problem Behaviour Checklist	Intention was weakly positively associated with adherence ($r = 0.21$, $p < .001$)
Guénette et al. (2016)	Canada	Diabetes	901	62.7 (9.1)	58.60	C	N/A	Self-report 6 items made for study	S	MMAS-8®	Intention was weakly positively associated with adherence ($r = 0.10$)
Hagger et al. (2016)	Australia	Familial hypercholesterolemia	110	50.65 (13.81)	43.64	C	N/A	Self-report 1 item made for study	S	Self-report over previous 3 months	Intention was strongly positively associated with adherence ($r = 0.635$, $p < .001$)
Ho & Lee (2014)	Taiwan	Hypertension	604	-	-	C	N/A	Self-report (unsure number of items)	S	MMAS-8®	Intention was moderately positively associated with adherence ($r = 0.49$, $p < .001$)

Holstad et al. (2006)	USA	HIV	120	36.5 (8.5)	60.0	C	N/A	Self-report 4 items from Antiretroviral Adherence Determination Questionnaire	S	Antiretroviral General Adherence Scale	Intention was weakly positively associated with adherence ($r = 0.19$, $p < .05$)
Hugon et al. (2014)	France	Organ Transplant	153	55.7 (13.0)	71.2	L	N/A	Self-report 2 items based on Chisholm et al. (2007)	CO	1. Plasma through concentrations of immunosuppressant over the 6 months preceding inclusion 2. Morisky Green Levine Medication Adherence Scale (MGLS)	Intention was weakly positively associated with adherence ($r = 0.25$, $p < .05$)
Hoo et al. (2019)	England	Cystic Fibrosis	61	-	54.1	L	3 months	Self-report 1 item adapted from COM-B Self-Evaluation Questionnaire	O	Chipped nebulisers	Intention was weakly positively associated with adherence ($r = 0.282$, $p = .028$)
Hoo et al. (2017)	England	Cystic Fibrosis	20	-	60.0	C	N/A	Self-report 2 items adapted from COM-B Self-Evaluation Questionnaire	O	I-neb (application) - % between total amount used against the agreed dosage	Intention was weakly negatively associated with adherence ($r = -0.093$, $p = .695$)
Jessop & Rutter (2003)	-	Asthma	330	57.2 (17.9)	33.3	C	N/A	Self-report 2 items made for study	S	Self-report 5 items made for study (over previous 3 months)	Intention was strongly positively associated with adherence ($r = 0.61$, $p < .001$)
McCloskey & Johnson (2019)	USA	Various	459	-	56.6	C	N/A	Self-report 1 item made for study	S	BehaviourQual 1 item	Intention was weakly positively associated with adherence ($r = 0.27$, $p < .001$)
Lin et al. (2016)	Iran	Epilepsy	567	38.37 (6.71)	48.5	L	24 months	Self-report 5 items based on Ajzen (1991)	S	MARS – 5 items	Intention was strongly positively associated with adherence ($r = 0.69$)

McDonnell et al. (2001)	USA	Tuberculosis	62	46.5 (11.6)	-	C	N/A	4 items from Tuberculosis Adherence Determination Questionnaire	S	Tuberculosis General Adherence scale (over previous 4 weeks)	Intention was weakly positively associated with adherence ($r = 0.29$, $p < .005$)
McKinney et al. (2015)	Malawi	HIV	358	-	0	C	N/A	Self-report 4 items based on Ajzen (1991)	S (but CO of two)	1. Two-day self-report recall of how many doses of medication patients took 2. One-month self-report recall by patient	Intention was very weakly positively associated with adherence ($r = 0.01$)
Molfenter et al. (2012)	USA	Cholesterol	1433	54.2 (9.79)	56.3	L	6 months	-	O	Past medication-refill behaviour using proportion of days covered (PDC)	Intention was moderately positively associated with adherence ($r = 0.41$)
Molloy et al. (2012)	Scotland	Oral Contraceptive Pill	130	20.46 (3.01)	-	C	N/A	Self-report 2 items made for study	S	MARS – 5 items (higher scores = non-adherence)	Intention was moderately negatively associated with adherence ($r = -0.33$, $p < .01$)
Moore (1995)* (A and B)	USA	Hypertension	100	66 (14.5)	23.0	C	N/A	Self-report 7 items made for study	S O	1. Time since last medication (in hours) 2. Urine levels of Hydrochlorothiazide (Hctz)	Intention was weakly negatively associated with ‘time since last medication’ adherence ($r = -0.26$, $p < .01$) and was weakly positively associated with urine levels of Hctz adherence ($r = 0.05$).
Nelsen et al. (2013)	USA	HIV	244	51.8 (9.5)	92.0	C	N/A	Self-report 13 items previously validated by the authors	S	Self-reported adherence in the previous month using a Visual Analogue Scale - 90% or below was considered non-adherent	Intention was weakly positively associated with adherence ($r = 0.25$)
Pakpour et al. (2014)	Iran	Coronary artery bypass surgery	223	59.21 (7.14)	76.2	L	12 months	Self-report 5 items adapted from previous research	S	MARS - 5 items	Intention was moderately positively associated with

											adherence ($r = 0.34, p < .01$)	
Peleg et al. (2017)	Israel	Cardiovascular disease	106	55.71 (7.87)	100	L	6 months	Self-report 1 item made for study	S	MARS – 5 items	Intention was moderately positively associated with adherence ($r = 0.47, p < .001$)	
Presseau et al. (2017)	Canada	Post-myocardial infarction	201	68.0 (12)	61.0	L	9 months	Self-report 3 items made for study	S	MMAS-8 [®]	Intention was weakly positively associated with adherence ($r = 0.05$)	
Putman (2004)	USA	Asthma	102	-	25.0	C	N/A	Asthma Behavioural Intention Instrument	S	Asthma Adherence Instrument	Intention was moderately positively associated with adherence ($r = 0.35$)	
Quine et al. (2012)	England	Hypertension	934	69.0 (11.7)	42.0	L	2 months	Self-report 4 items made for study	S	Morisky Medication Adherence Scale 4 items (MMAS-4) and 1 additional item made for study	At follow-up, intention was weakly positively associated with adherence ($r = 0.24, p < .001$)	
Scholz et al. (2012)	Switzerland	Organ transplant	121	54.32 (13.32)	67.0	C	N/A	Self-report 4 items adapted from Chisholm et al. (2007)	S	Adherence subscale from the German version of the Transplant Effects Questionnaire (TxEQ-D)	Intention was moderately positively associated with adherence ($r = 0.54$)	
Author and year	Country	Illness of interest	Total N	Mean age (SD) of sample	% of sample male	Study design	Length of follow-up	Measure of variable		Measure of medication adherence		Results
										Type of measure	Name	
Behavioural Prepotency Meta-Analysis												
Burns et al. (2019)	Canada	Type 2 Diabetes	790	64.05 (8.20)	50.8	C	N/A	SRBAI – 4 items	S	2 items made for study		Habit was weakly positively associated with adherence ($r = 0.16, p < .001$)
Cook et al. (2015)* (A and B)	USA	Glaucoma	201	65.0 (11.2)	27.69	L	2 months	Cues to action (within the Glaucoma	O	1. MEMS [®]		Cues to action was weakly negatively associated with MEMS adherence ($r = -$

								Treatment Compliance Assessment Tool)		2. Adherence attitude Inventory – 6 days retrospective	0.27) and moderately weakly associated with subjective adherence ($r = -0.35$).
Durand et al. (2018) (A, B, C and D)	Ireland	Hypertension	2014	69.86 (10.69)	57.8	C	N/A	SRBAI – 4 items	S	1. MMAS-8 [®]	Habit was moderately positively associated with MMAS-8 adherence ($r = 0.35$, $p < .001$), MARS-5 adherence ($r = 0.36$, $p < .001$), was weakly positively associated with prescription refill records ($r = 0.08$) and weakly negatively associated with urine samples ($r = -0.02$).
									S	2. MARS-5	
									O	3. Prescription refill records	
									O	4. Biochemical assay of urine	
Guénette et al. (2016)	Canada	Diabetes	901	62.7 (9.1)	58.6	C	N/A	SRBAI – 4 items	S	MMAS-8 [®]	Habit was weakly positively associated with adherence ($r = 0.16$, $p < .001$).
Hoo et al. (2017)	England	Cystic Fibrosis	20	-	60.0	C	N/A	SRBAI – 4 items	O	I-neb (application) - % between total amount used against the agreed dosage	Habit was strongly positively associated with adherence ($r = 0.64$, $p = .002$).
Hoo et al. (2019)	England	Cystic Fibrosis	61	N/A	54.1	L	3 months	SRBAI – 4 items	O	Chipped nebulisers	Habit was strongly positively associated with adherence ($r = 0.57$, $p < .001$).
Ikechuwku et al. (2010)	Nigeria	Hypertension	756	56.5 (14.4)	63.8	C	N/A	Interview	S	“Pills taken over a specific period of time, divided by pills prescribed for that specific period of time” (3, 5, 7 days retrospective). Score was expressed as the average percentage of adherence across the three measurements	Habit was strongly positively associated with adherence ($r = 0.60$, $p < .001$).

McCloskey & Johnson (2019)	USA	Varied	459	-	56.6	C	N/A	SRBAI – 4 items	S	BehaviourQual 1 item	Habit was moderately positively associated with adherence ($r = 0.48$, $p < .001$)
Murphy et al. (2018)	Ireland	Oral Contraceptive Pill	245	22.41 (4.78)	0.0	C	N/A	SRBAI – 4 items	S	MARS-5	Habit was weakly positively associated with adherence ($r = 0.24$, $p < .001$)
Phillips et al. (2013) (A, B, C and D)	USA	Hypertension	71	67.90 (12.28)	37.0	L	1 month	SRHI and 4 items made for study	S	1. MARS-5	Habit was moderately positively associated with both MARS-5 adherence ($r = 0.37$, $p < .01$) and MMAS-8 adherence ($r = 0.26$, $p < .05$) and moderately to strongly associated with MEMS (frequency) ($r = 0.42$, $p < .01$) and MEMS (time) ($r = 0.49$, $p < .01$)
									S	2. MMAS-8 [®]	
									O	3. MEMS [®] (frequency)	
									O	4. MEMS [®] (time)	
Phillips et al. (2016) (A, B and C)	USA	Type 2 diabetes	133	56.96 (12.04)	38.0	L	1 month	SRBAI – 4 items	S	1. MARS-5	Habit was moderately associated with MARS-5 adherence ($r = 0.40$, $p < .001$), and both MEMS (frequency) ($r = 0.37$, $p < .001$) and MEMS (time) ($r = 0.40$, $p < .001$)
									O	2. MEMS [®] (frequency)	
									O	3. MEMS [®] (time)	
Widjanarko et al. (2018)	Indonesia	Lymphatic filariasis (from mosquitos)	600	38.8	31.7	C	N/A	Self-report cues to action (specifically internal and external) – made for study	-	-	No results reported for external cues. But internal cues were moderately positively associated with adherence ($r = 0.33$)
Wolkovich (2017)*	Israel	Multiple Sclerosis	96	41.9 (14.0)	29.2	L	6 months	SRHI – 12 items	S	Probabilistic Medication Adherence Scale (ProMAS)	Habit was weakly positively associated with adherence ($r = 0.04$, $p = .224$)

Author and year	Country	Illness of interest	Total N	Mean age (SD) of sample	% of sample male	Study design	Length of follow-up	Measure of variable	Measure of medication adherence	Results	
Self-regulatory Capacity Meta-Analysis											
									Type of measure	Name	
Bolman et al. (2011)	USA	Asthma	139	31.5 (5.6)	29.5	C	N/A	SRHI – 12 items	S	MARS-5	Habit was strongly positively associated with adherence ($r = 0.61$, $p < .001$)
Attonito (2013)*	USA	HIV / AIDS	246	45.24 (7.04)	66.0	C	N/A	Executive function 1. The Colour Trails Test 2, Form A 2. The Category Test Short Form	S	Percentage of time ART medications were taken as prescribed over the course of a week	Executive function (composite measure) was positively weakly associated with adherence ($r = 0.06$)
Baek (2015)* (1 and 2)	USA	Type 2 diabetes or diabetes related condition	104	56.40 years (9.3)	33.7	L	3 months	Executive function 1. Stroop Colour Word Test 2. Controlled Oral Word Association Test (COWAT) 3. Trail Making Test B	O S	1. MEMS® 2. MMAS-8®	Executive function (composite measure) was weakly negatively associated with MEMS adherence ($r = -0.13$, $p = .521$) and weakly positively associated with MMAS-8 adherence ($r = 0.06$, $p = .948$)
Banas et al. (2017)	Tanzania	HIV /AIDS	158	43.75 years (10.5)	30.7	L	5 months	Self-regulation 4 items made for study	O	MEMS®	Self-regulation was weakly associated with adherence at 5 months ($r = 0.19$, $p < .05$)
Bourdeau (2004)*	USA	Haemodialysis	82	59.7 (15.0)	55.0	L	3 months	Self-control Rosenbaum's Self-Control Schedule	S	1 item made for study	Self-control was weakly positively associated with adherence ($r = 0.19$, $p = .025$)
Boyer et al. (2012) (1, 2, 3 and 4)	France	Schizophrenia	169	36.6 (12.5)	73.4	C	N/A	Executive function 1. Stroop Colour-Word Test	S	Medication Adherence Rating Scale (MARS) - 10	Executive function as measured by Stroop was weakly and negatively associated with adherence

									2. Verbal Fluency Test (letter and category domains) 3. Trail Making Test A 4. Trail making Test B			($r = -0.14$). Executive function as measured by the two domains of the Verbal Fluency Test were also weakly and negatively associated with adherence ($r = -0.02$ and $r = -0.01$, respectively). Trail making tests A and B were both weakly but positively associated with adherence ($r = 0.05$, and $r = 0.08$, respectively)
Casaleto et al. (2016)	USA	Bipolar disorder	50	47.1 (9.7)	88.0	L	1 month	Executive function 1. Wisconsin Card Sorting Task 2. Trail making Test B	O	MEMS®		Executive function (composite measure) was weakly positively associated with adherence ($r = 0.24$, $p = .100$)
Cholowski & Cantwell (2007)	Australia	Heart failure	51	72.3 (8.19)	-	C	N/A	Self-regulation 10 items made for study	S	Self-report during interview		Self-regulation was weakly positively associated with adherence ($r = 0.17$)
Contardo et al. (2009)	USA	HIV	99	44.5 (7.5)	58.8	L	4 weeks	Executive function 1. Trail Making Test A 2. Trail Making Test B	O	MEMS®		Executive function (composite measure) was weakly negatively associated with adherence ($r = -0.11$)
de Bruin, et al. (2012)	The Netherlands	HIV	56	48.9 (9.1)	88.0	L	3 months	Self-regulation 3 items made for study	CO	1. MEMS® 2. Self-report 1 item		Self-regulation was strongly positively associated with adherence ($r = 0.63$, $p < .001$)
Dolansky et al. (2016)	USA	Heart failure	144	68.7 (9.7)	59.7	L	3 weeks	Executive function 1. Stroop Colour-Word Task 2. Trail Making Test B 3. Frontal Assessment Battery	O	MedSignals Pillbox		Executive function (composite measure) was moderately positively associated with adherence ($r = 0.29$)

El-Missiry et al. (2015)	Egypt	Schizophrenia	137	32.3 (9.0)	70.6	L	6 months	Executive function Wisconsin Card Sorting Task (computer version)	O	Brief Adherence Rating Scale (BARS)	Executive function was strongly positively associated with adherence ($r = 0.50, p = .271$)
Ettenhofer et al. (2009) 1	USA	HIV	79	53.03 (4.46)	81.0	C	N/A	Executive function 1. Trail Making Test B 2. Stroop Colour-Word 3. Short Category Test 4. Wisconsin Card Sorting Task	CO	1. MEMS® 2. Number of doses of the MEMS-tracked medication missed 3. Report of whether they missed a dose of their MEMS medication the previous day 4. Medical Outcome Scale questionnaire	Executive function (composite) was moderately positively associated with the composite adherence measure ($r = 0.41, p < .01$).
Ettenhofer et al. (2009) 2	USA	HIV	352	40.49 (5.53)	80.4	C	N/A	Executive function 1. Trail Making Test B 2. Stroop Colour-Word 3. Short Category Test 4. Wisconsin Card Sorting Task	CO	1. MEMS® 2. Number of doses of the MEMS-tracked medication missed 3. Report of whether they missed a dose of their MEMS medication the previous day 4. Medical Outcome Scale questionnaire	Executive function (composite) was weakly positively associated with the composite adherence measure ($r = 0.02, p = .730$).
Ettenhofer et al. (2010)	USA	HIV	91	42.25 (7.71)	78.0	L	6 months	Executive function (no other details reported)	O	MEMS®	Executive function was moderately positively associated with adherence measure ($r = 0.31$).
Feldman (2003)* (1 and 2)	Canada	Various	92	76.82 (6.46)	32.61	L	1 week	Executive function 1. Similarities subtest from the	S	1. Brief Medication Questionnaire (BMQ)	Executive function (composite) was weakly negatively associated with

								WAIS-III 2. Trail Making Test 3. Stroop Colour-Word 4. Controlled Oral Word Association Test (FAS) 5. Rule Shift Cards Test from the Behavioural Assessment of Dysexecutive Syndrome (BADS) 6. Action Program Test from the BADS	S	2. Reported Adherence to Medication Scale (RAMS)	BMQ adherence ($r = -0.26$, $p = .05$) and moderately weakly associated with RAMS adherence ($r = -0.38$, $p < .001$).
Gelb et al. (2010) (1 and 2)	Canada	Kidney transplant	103	50.07 (12.38)	52.7	C	N/A	Executive function 1. Trail Making Test 2. Stroop Colour-Word	S	Immunosuppressant adherence subscale from the Transplant Effects Questionnaire (TxEQ)	Executive function as measured by the Trail Making task was weakly negatively associated with adherence ($r = -0.16$) and executive function as measured by the Stroop Colour-Word test was weakly negatively associated with adherence ($r = -0.05$).
Hinkin et al. (2002)	USA	HIV	137	44.1 (7.5)	82.0	C	N/A	Neuropsychological domain - measure contains 3 measures of executive function	O	MEMS®	The neuropsychological domain was moderately positively associated with adherence ($r = 0.30$, $p = .030$).
Hinkin et al. (2004)	USA	HIV	148	44.2 (7.7)	83.0	L	4 weeks	Executive function 1. Short Category Test 2. Trail Making Test B 3. Stroop Colour-Word	O	MEMS®	Poor executive function (composite measure) was strongly positively associated with poor adherence ($r = 0.53$).

Hoo et al. (2017)	England	Cystic Fibrosis	20	-	60.0	C	N/A	Self-control Brief Self Control Scale (BSCS)	O	I-neb (application) - % between total amount used against the agreed dosage	Self-control was moderately positively associated with adherence ($r = 0.44$).
Insel et al. (2006)	USA	Various	95	78.0	22.0	L	2 months	Executive function and working memory (composite) 1. Wisconsin Card Sorting Task 2. Wechsler Memory Scale 3 - letter-number sequence, mental control, and digit span backward	O	MEMS®	The composite of executive function and working memory was moderately positively associated with adherence ($r = 0.40$, $p < .01$).
Insel et al. (2008) (1 and 2)	USA	Hypertension	16	70.19	56.25	L	2 months	Executive function 1. Executive Exit Interview 2. Wisconsin Card Sorting Task	O	MEMS®	Executive function as measured by the Executive Exit Interview was moderately negatively associated with adherence ($r = -0.45$). Executive function as measured by the 'categories completed' score of the Wisconsin Card Sorting Task was weakly positively associated with adherence ($r = 0.19$).
Kosilov et al. (2019)	Russia	Overactive bladder	364	73.6 (8.1)	0.0	L	3 months	Executive function and working memory (composite) 1. Wisconsin Card Sorting test 2. Wechsler Memory Scale 3 3. California Verbal Learning Test	O	MEMS®	Executive function and working memory composite measure was moderately positively associated with adherence ($r = 0.47$, $p < .001$).

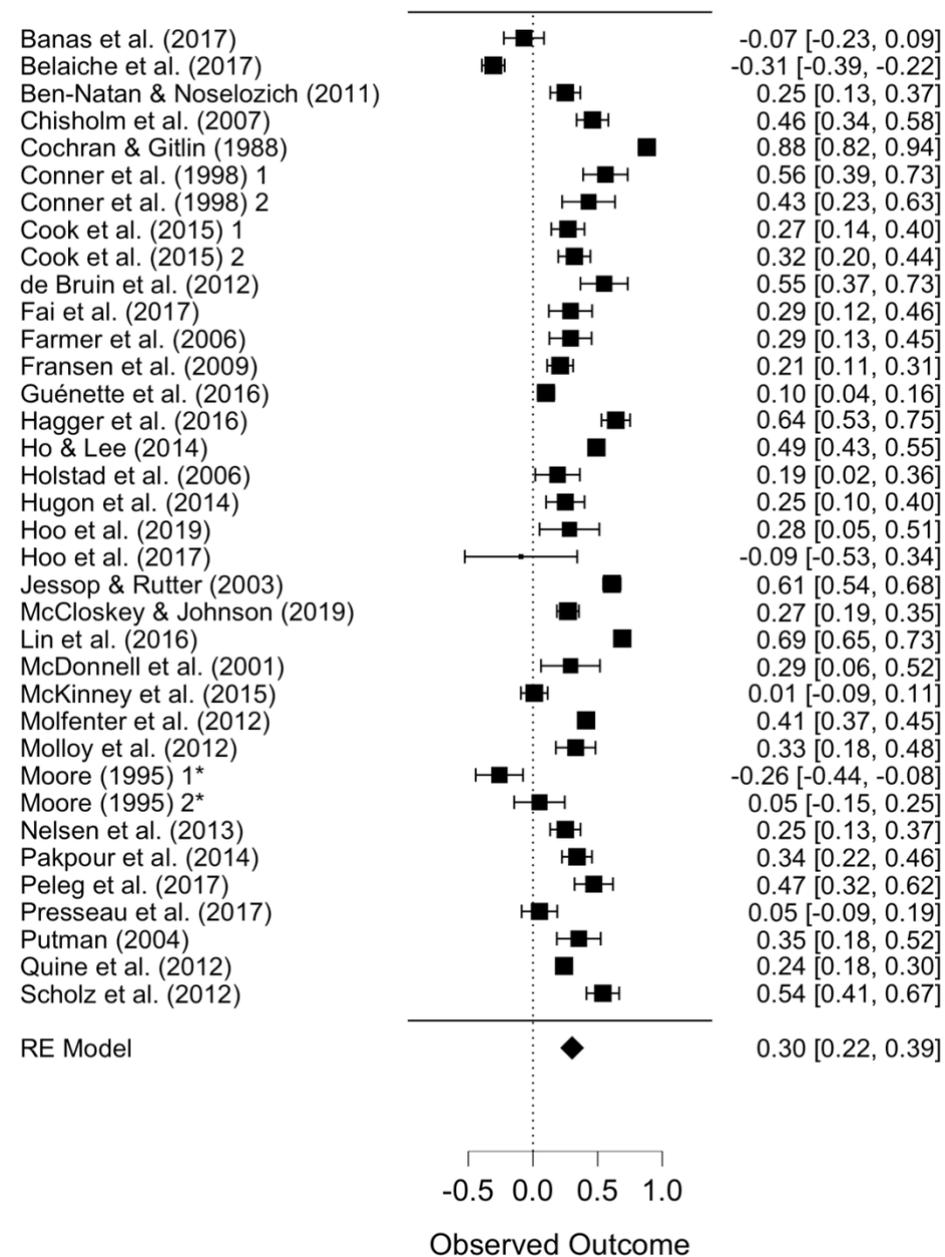
Kowalczyk (2012)* (1 and 2)	USA	HIV	156	41.1 (8.7)	100.0	C	N/A	Executive function Wisconsin card sorting task (categories completed)	S S	1. Timeline Follow-Back 2. Visual Analogue Scale	Executive function as measured by the 'categories completed' score of the Wisconsin Card Sorting Task was weakly positively associated with Timeline-Follow-Back adherence ($r = 0.084$) and weakly positively associated with the Visual Analogue Scale adherence score ($r = 0.136$).
Lee (2018)* (1 and 2)	USA	HIV	94	Age range 40-59 years	-	C	N/A	Executive function Wisconsin Card Sorting Task (categories completed)	O S	1. Pharmacy Refill Rates (2 months prior to study) 2. MMAS-8 [®]	Executive function as measured by the 'categories completed' score of the Wisconsin Card Sorting Task was moderately positively associated with Pharmacy Refill Rates adherence ($r = 0.42$, $p = .225$) and weakly positively associated with MMAS-8 adherence ($r = 0.140$, $p = .590$).
O'Connor et al. (2019) (1 and 2)	USA	COPD	388	68.0 (8.3)	41.7	L	12 months and 24 months	Executive function 1. Trail making Test A 2. Trail making Test B	S	MARS-10	Executive function as measured by the Trail Making Test A was weakly positively associated with adherence ($r = 0.084$). When measured using the Trail Making Test B it, executive function and adherence were weakly positively associated ($r = 0.052$).
O'Connor et al. (2015)	USA	Asthma	425	67.4 (6.8)	16.5	C	N/A	Fluid abilities composite	S	MARS-10	Fluid ability was weakly positively associated with

								(processing speed, working memory, long-term memory, executive function, and global cognitive function) 1. Pattern Comparison 2. WMS Letter-Number Sequencing 3. WMS 2 story A 4. Trails Making Task A and B 5. Mini-Mental State Exam				adherence ($r = 0.17$, $p < .001$).
Schutte (2006)* (1, 2, 3 and 4)	USA	Various	30	75.0 (7.1)	63.3	L	2 weeks	Executive function 1. Stroop Colour-Word 2. Tower of London 3. Trail Making Test B 4. Digit span	O	MEMS®		Executive function as measured by the Stroop Colour-Word Test was weakly positively associated with adherence ($r = 0.285$). Tower of London was also weakly positively associated with adherence ($r = 0.086$). Trail Making Test B and Digit Span were also both weakly positively associated with adherence ($r = 0.010$, and $r = 0.034$ respectively).
Stilley et al. (2010) A	USA	High cholesterol	157	46.2 (8.7)	54.1	L	6 months	Executive function (composite) 1. Trails Making Test B 2. Digit Span	O	MEMS®		Executive function was weakly negatively associated with adherence ($r = -0.179$).
Stilley et al. (2010) B	USA	Diabetes/hypertension	354	63.7 (10.3)	40.5	L	24 days	Executive function Stroop Colour-Word Test	O	MEMS®		Executive function was very weakly positively associated with adherence ($r = 0.001$).

Stilley et al. (2010) C	USA	Breast cancer	34	59.76 (4.66)	0.0	L	6 months	Executive function (composite) 1. Controlled Oral Word Association 2. Stroop Colour-Word 3. Stockings of Cambridge	O	MEMS®	Executive function was moderately positively associated with adherence at 6 months ($r = 0.384$)
Stoehr et al. (2008)	USA	Various	342	77.52 (6.71)	30.62	C	N/A	Executive function 1. Trails Making Test B	S	Nurse assessment	Executive function was moderately positively associated with adherence at 6 months ($r = 0.377$, $p = .02$)
Thames et al. (2011)	USA	HIV	51	48.2 (13.8)	76.9	C	N/A	Executive function (measures made into composite with all other neuropsychological measures) 1. Trail Making Test B 2. Wisconsin Card Sorting Task 3. Stroop Colour-Word	S	Percentage of antiretroviral medication doses taken over the last 30 days	Total neuropsychological functioning was weakly positively associated with adherence ($r = 0.13$, $p = .390$)
Waldrop-Valverde et al. (2006)	USA	HIV	57	42.75 years (5.6)	3.5	C	1 week	Executive function (composite) 1. Colour Trails Test 1 and 2 2. Digit Span 3. Controlled Oral Word Association Test	S	Interviewer-administered questionnaire	Executive function was very weakly positively associated with adherence ($r = 0.001$).

Note. *indicates unpublished research, *N* = sample size, *C* = cross-sectional design, *L* = longitudinal design, *S* = subjective measure of medication adherence, *O* = objective measure of medication adherence, *CO* = composite measure of medication adherence. A number/s (i.e., 1 and 2) besides author name indicates multiple measures of variable of interest or medication adherence and thus included in the analysis more than once. A letter (i.e., *B*) besides author name indicates a different sample within the same study.

Figure 2.2

Forest Plot of the Association Between Intention and Medication Adherence

Note. *Unpublished research

A number/s (i.e., 1 and 2) besides author name indicates multiple measures of variable of interest or medication adherence and thus included in the analysis more than once.

Figure 2.3

Funnel Plot Showing the Publication Bias for the Association Between Intention and Medication Adherence

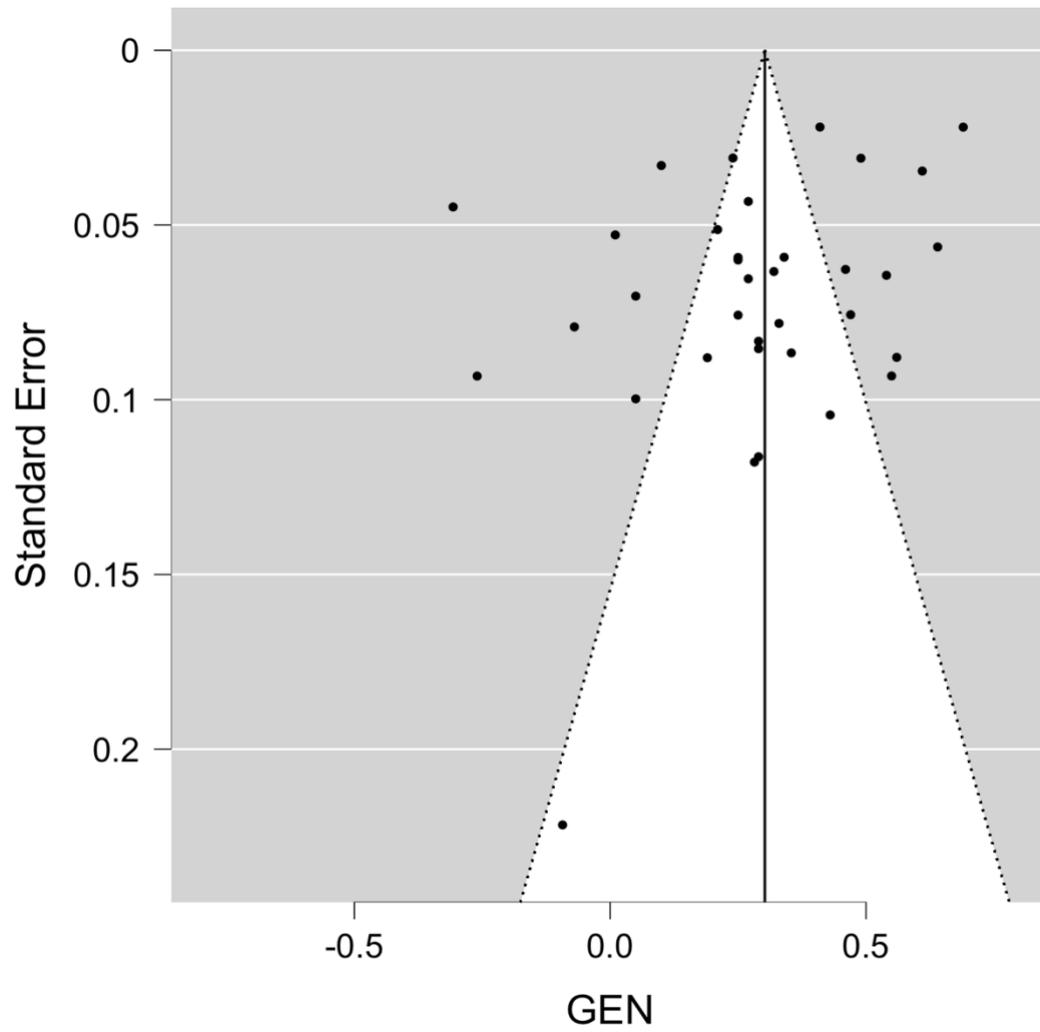
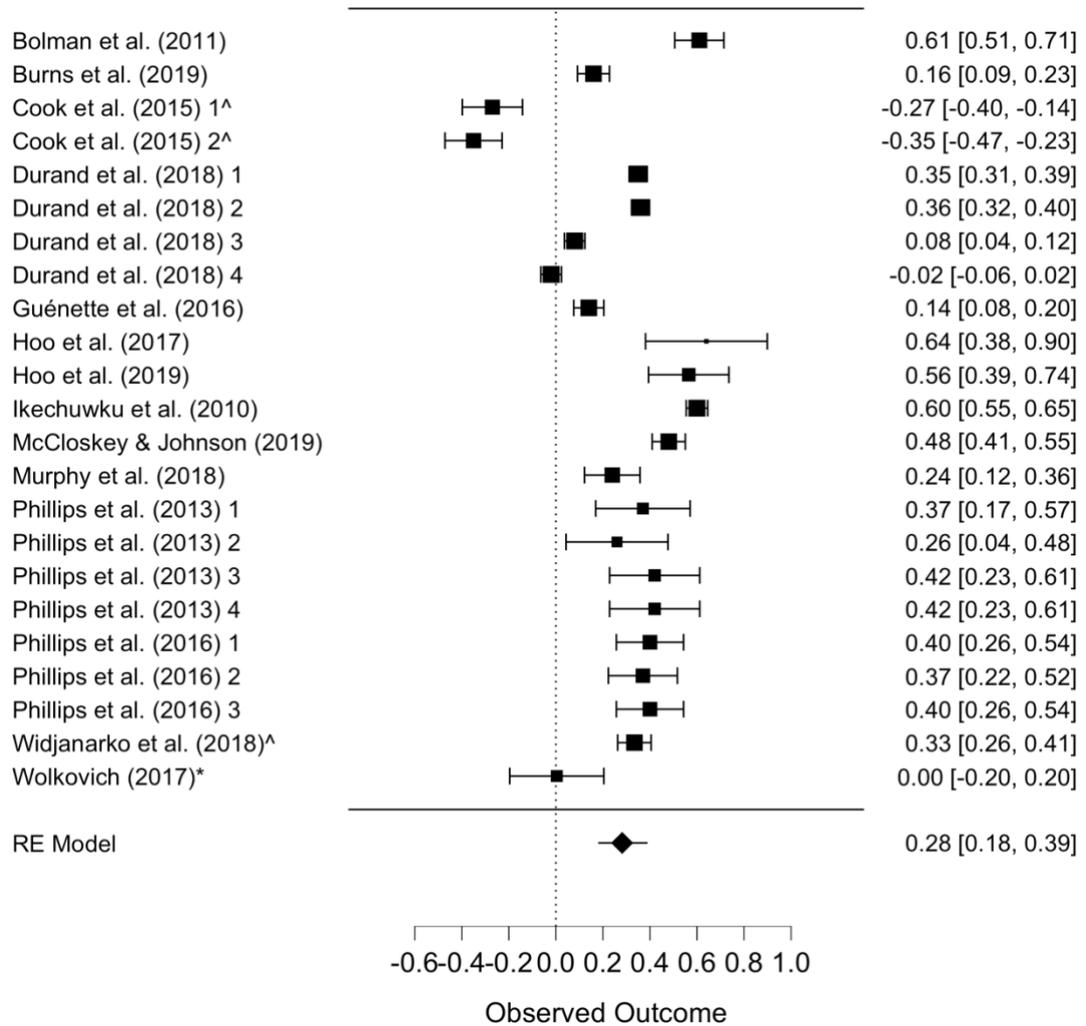


Figure 2.4

Forest Plot of the Association Between Behavioural Prepotency and Medication Adherence



Note. ^Measure of behavioural prepotency was Cues to Action.

*Unpublished research

A number/s (i.e., 1 and 2) besides author name indicates multiple measures of variable of interest or medication adherence and thus included in the analysis more than once.

Figure 2.5

Funnel Plot Showing the Publication Bias for the Association Between Behavioural Prepotency and Medication Adherence

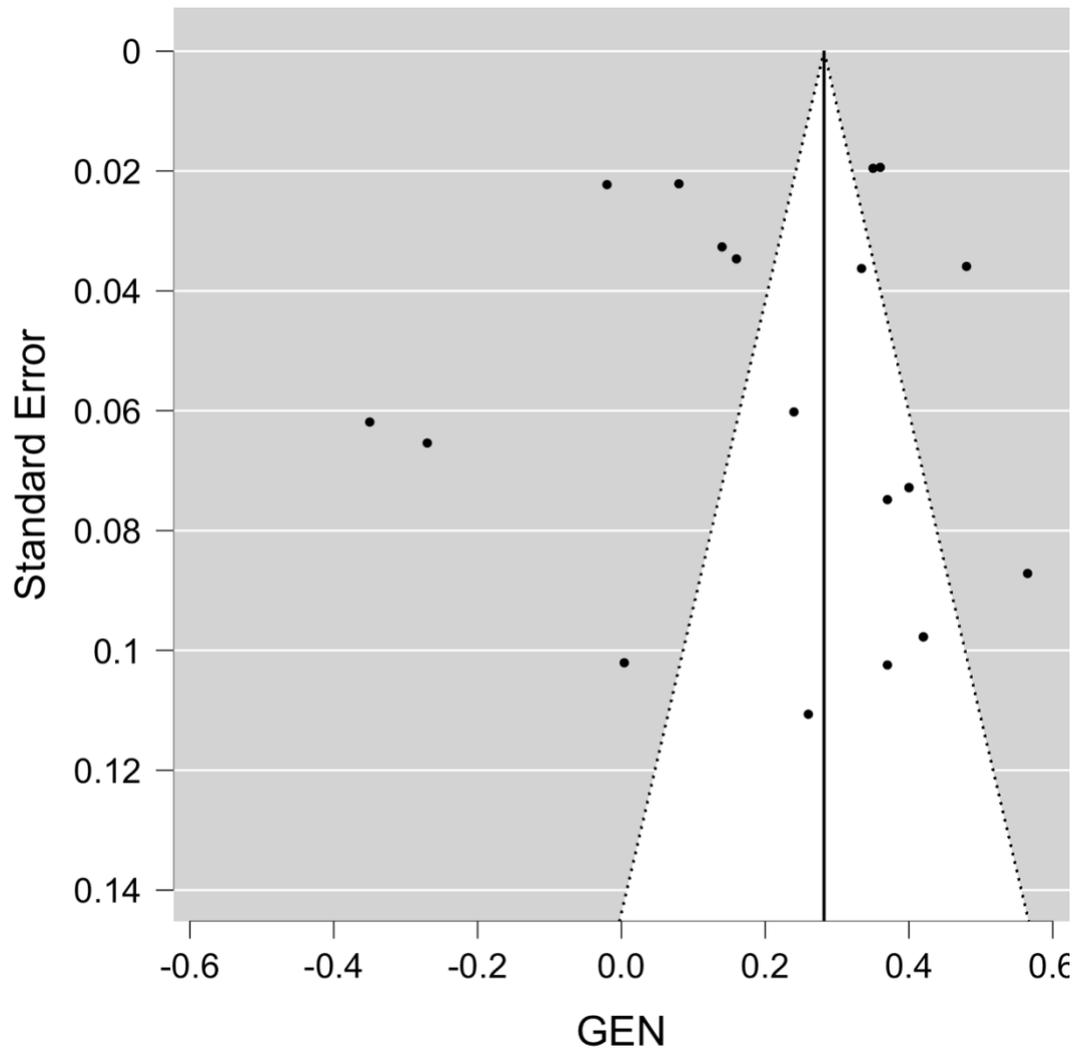
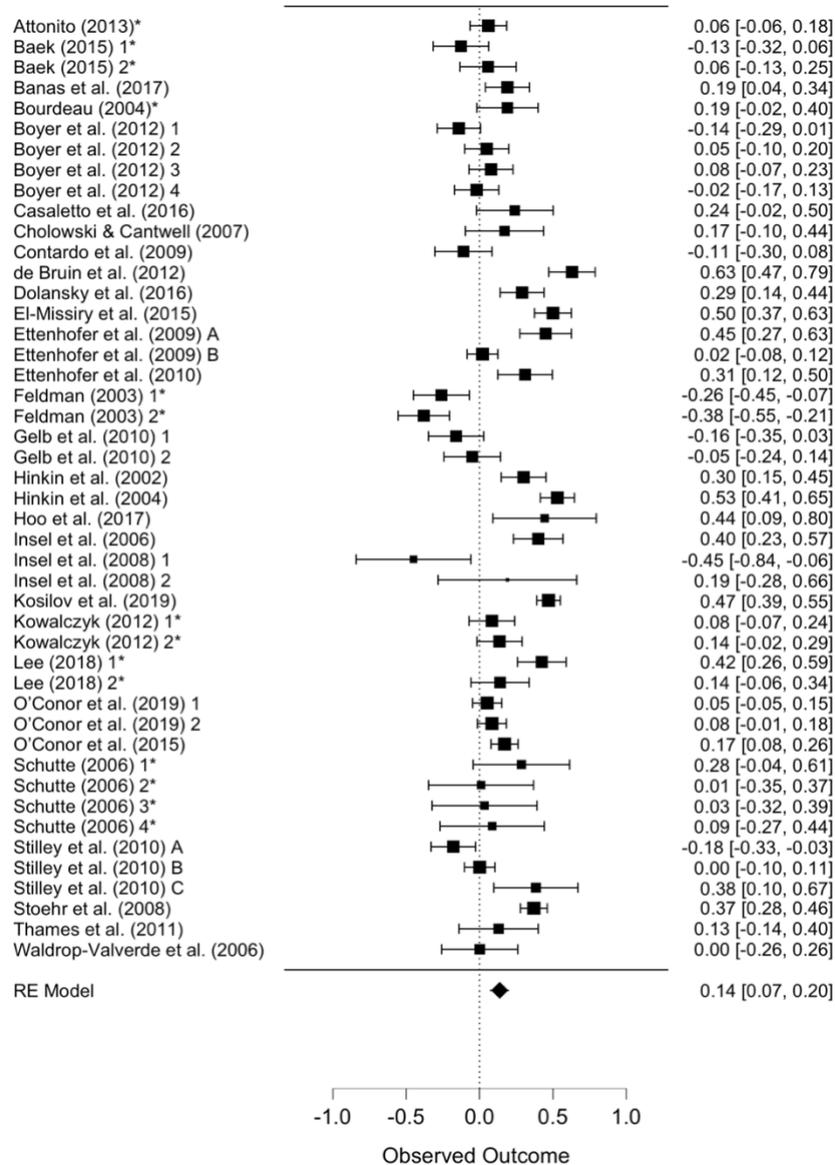


Figure 2.6

Forest Plot of the Association Between Self-Regulatory Capacity and Medication Adherence



Note. *Unpublished research

A number/s (i.e., 1 and 2) besides author name indicates multiple measures of variable of interest or medication adherence and thus included in the analysis more than once. A letter (i.e., B) besides author name indicates a different sample within the same study.

Figure 2.7

Funnel Plot Showing the Publication Bias for the Association Between Self-Regulatory Capacity and Medication Adherence

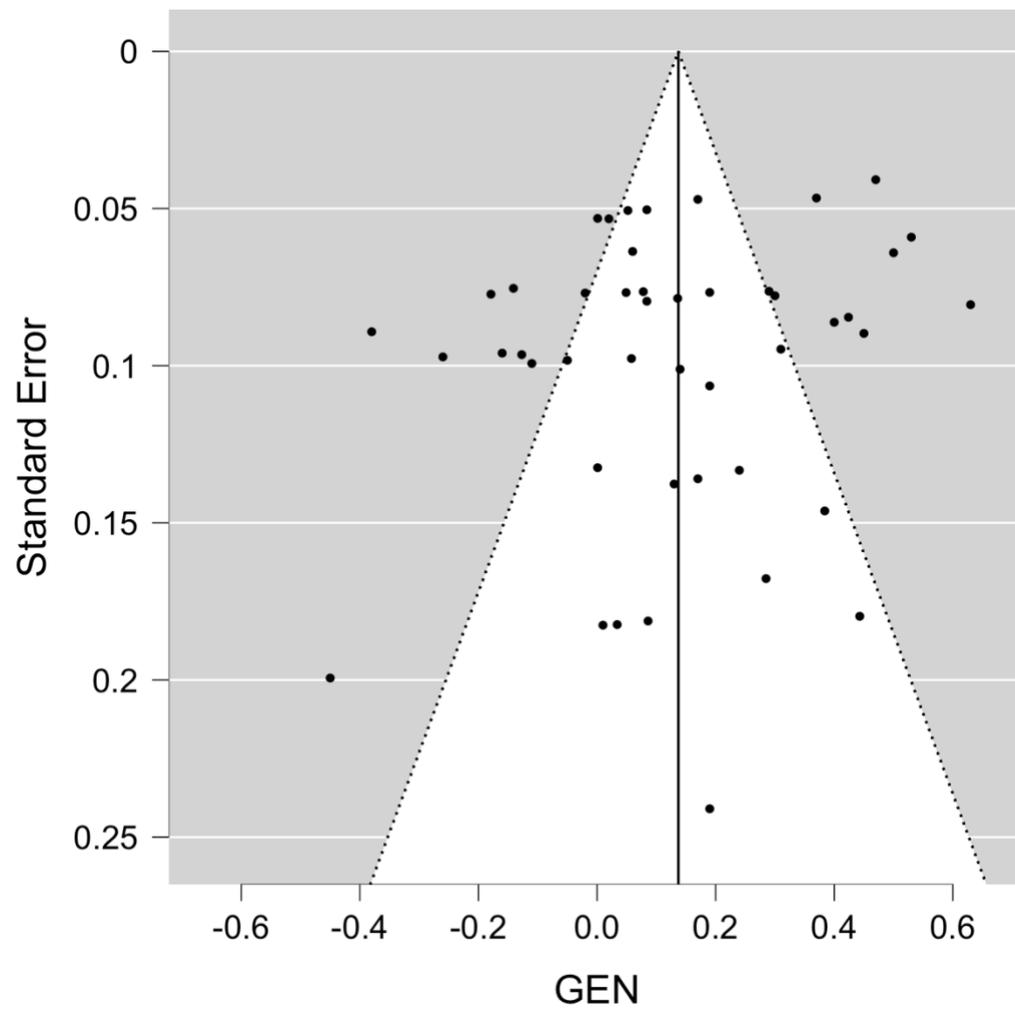


Table 2.3*Moderator Analysis for the Associations Between the Three Temporal Self-Regulation Theory Constructs and Medication**Adherence*

	Intention			Behavioural Prepotency			Self-regulatory Capacity		
	<i>B</i> (95% CI)	<i>z</i>	<i>I</i> ²	<i>B</i> (95% CI)	<i>z</i>	<i>I</i> ²	<i>B</i> (95% CI)	<i>z</i>	<i>I</i> ²
Chronic^a	-0.09 (-0.40, 0.22)	-0.58	95.98%	-0.22 (-0.59, 0.15)	-1.15	97.74%	-0.02 (-0.45, 0.40)	-0.10	87.63%
Longitudinal^b	0.05 (-0.11, 0.22)	0.63	95.78%	-0.10 (-0.31, 0.12)	-0.86	97.83%	0.00 (-0.14, 0.14)	0.05	87.95%
Objective^c	-0.11 (-0.29, 0.45)	-0.99	95.70%	0.06 (-0.17, 0.29)	0.62	97.73%	0.13 (-0.00, 0.27)	1.92	86.07%
Composite^c	0.08 (-0.29, 0.45)	0.42	95.70%	-	-	-	0.30 (0.04, 0.55)*	2.25	86.07%
Cues to action^d	-	-	-	0.42 (0.16, 0.69)**	3.20	96.76%	-	-	-
Fluid ability^e	-	-	-	-	-	-	0.06 (-0.38, 0.49)	0.26	87.80%
Total cognitive functioning^e	-	-	-	-	-	-	0.02 (-0.49, 0.52)	0.06	87.80%
Self-control^e	-	-	-	-	-	-	0.18 (-0.18, 0.55)	0.99	87.80%
Self-regulation^e	-	-	-	-	-	-	0.23 (-0.05, 0.50)	1.61	87.80%
Attitudes/beliefs^f	-0.12 (-0.34, 0.12)	-0.92	95.25	-0.66 (-1.01, -0.31)**	-3.73	94.07%	-0.08 (-0.25, 0.10)	-0.86	85.07%

Note. ^a in comparison with acute, ^b in comparison with cross-sectional, ^c in comparison with subjective measures, ^d in comparison with habit strength, ^e in comparison to executive function specifically, ^f in comparison to subjective measures of behaviour (e.g., MARS-5, MMAS-8)

** $p < .001$ * $p < .05$

Table 2.4*Study Quality and Risk of Bias of Each Study Included in the Analysis*

Author and Year	Criteria 1	Criteria 2	Criteria 3	Criteria 4	Criteria 5	Criteria 6	Criteria 7	Criteria 8	Criteria 9	Criteria 10	Criteria 11	Criteria 12	Criteria 13	Criteria 14	Overall quality
Attonito (2013)	Y	Y	Y	Y	Y	N	N	NA	Y	N	Y	NA	NA	N	Good
Baek (2015)	Y	N	CD	Y	Y	Y	Y	NA	Y	N	Y	NA	NR	Y	Good
Banas et al. (2017)	Y	Y	CD	Y	N	Y	Y	NA	Y	N	Y	NA	Y	Y	Good
Belaiche et al. (2017)	Y	N	CD	Y	N	N	N	NA	Y	N	Y	NA	NA	N	Poor
Ben-Natan & Noselozich (2011)	Y	Y	CD	Y	N	N	N	NA	CD	N	N	NA	NA	N	Poor
Bolman et al. (2011)	Y	N	N	Y	Y	N	N	NA	Y	N	Y	NA	NA	Y	Fair
Bourdeau (2004)	Y	N	Y	Y	Y	Y	Y	NA	Y	N	Y	NA	NR	Y	Good
Boyer et al. (2012)	Y	Y	CD	Y	N	N	N	NA	Y	N	Y	NA	NA	N	Fair
Burns et al. (2019)	Y	Y	NR	Y	Y	N	N	NA	Y	N	CD	NA	NA	Y	Fair
Casaletto et al. (2016)	Y	N	CD	Y	Y	N	N	NA	Y	N	Y	NA	NA	N	Fair
Chisholm et al. (2007)	Y	Y	Y	Y	N	N	N	NA	Y	N	Y	NA	NA	Y	Fair
Cholowski & Cantwell (2007)	Y	Y	CD	Y	N	N	N	NA	Y	N	Y	NA	NA	N	Fair
Cochran & Gitlin (1988)	Y	N	N	Y	N	N	N	NA	Y	N	Y	NA	NA	N	Poor
Conner et al. (1998)	Y	N	Y	Y	Y	Y	Y	NA	Y	N	Y	NA	CD	N	Good
Contardo et al. (2009)	Y	N	CD	Y	N	Y	Y	NA	Y	N	Y	NA	NR	Y	Good
Cook et al. (2015)	Y	Y	CD	Y	Y	N	CD	NA	Y	N	Y	NA	NR	N	Fair
de Bruin et al. (2012)	Y	Y	Y	Y	Y	Y	Y	NA	Y	N	Y	NA	Y	Y	Good
Dolansky et al. (2016)	Y	N	CD	Y	N	Y	Y	NA	Y	N	Y	NA	NR	Y	Good
Durand et al. (2018)	Y	N	Y	Y	Y	N	N	NA	Y	N	Y	NA	NA	N	Fair

El-Missiry et al. (2015)	Y	N	CD	Y	N	Y	Y	NA	Y	N	Y	Y	Y	N	Good
Ettenhofer et al. (2009)	Y	N	CD	Y	Y	N	N	NA	Y	N	Y	NA	NA	Y	Fair
Ettenhofer et al. (2010)	Y	Y	CD	Y	Y	Y	Y	NA	Y	N	Y	NA	CD	Y	Good
Fai et al. (2017)	Y	N	CD	Y	N	N	N	NA	N	N	N	NA	NA	N	Poor
Farmer et al. (2006)	Y	N	Y	Y	N	N	N	NA	N	N	Y	NA	NA	N	Poor
Feldman (2003)	Y	N	CD	Y	N	Y	CD	NA	Y	N	Y	NA	Y	Y	Good
Fransen et al. (2009)	Y	N	CD	Y	N	Y	CD	NA	Y	N	Y	NA	Y	N	Fair
Gelb et al. (2010)	Y	Y	Y	Y	Y	N	N	NA	Y	N	Y	NA	NA	N	Good
Guénette et al. (2016)	Y	Y	N	Y	Y	N	N	NA	Y	N	Y	NA	NA	N	Fair
Hagger et al. (2016)	Y	N	Y	Y	Y	N	N	NA	Y	N	N	NA	NA	N	Poor
Hinkin et al. (2002)	Y	N	CD	Y	Y	N	N	NA	Y	N	Y	NA	NA	Y	Fair
Hinkin et al. (2004)	Y	N	CD	Y	N	N	N	NA	Y	N	Y	NA	CD	N	Fair
Ho & Lee (2014)	Y	N	CD	CD	N	N	N	NA	NR	N	NR	NA	NA	N	Poor
Holstad et al. (2006)	Y	N	CD	Y	N	N	N	NA	Y	N	Y	NA	NA	Y	Fair
Hoo et al. (2017)	Y	Y	Y	Y	Y	N	N	NA	Y	N	Y	NA	NA	N	Good
Hoo et al. (2019)	Y	N	CD	CD	Y	Y	Y	NA	Y	N	Y	NA	CD	N	Fair
Hugon et al. (2014)	Y	Y	N	Y	Y	N	NA	NA	Y	N	Y	NA	NA	N	Fair
Ikechuwku et al. (2010)	Y	Y	CD	Y	Y	N	N	NA	N	N	N	NA	NA	Y	Poor
Insel et al. (2006)	Y	N	CD	Y	Y	Y	Y	NA	Y	N	Y	NA	Y	Y	Good
Insel et al. (2008)	Y	N	CD	Y	N	Y	Y	NA	Y	N	Y	NA	CD	N	Fair
Jessop & Rutter (2003)	Y	N	N	Y	N	N	N	NA	Y	N	Y	NA	NA	N	Poor
Kosilov et al. (2019)	Y	Y	CD	Y	Y	Y	Y	NA	Y	N	N	NA	Y	N	Good
Kowalczyk (2012)	Y	N	CD	Y	Y	Y	Y	NA	Y	N	Y	NA	N	N	Good
Lee (2018)	Y	Y	N	Y	Y	N	N	NA	Y	N	Y	NA	NA	Y	Fair
Lin et al. (2016)	Y	Y	Y	Y	Y	Y	Y	NA	Y	N	Y	NA	CD	N	Good
McCloskey & Johnson (2019)	Y	N	NR	Y	CD	N	N	NA	Y	N	N	NA	NA	Y	Poor

McDonnell et al. (2001)	Y	Y	NR	Y	Y	N	N	NA	Y	N	Y	NA	NA	N	Fair
McKinney et al. (2015)	Y	Y	Y	Y	Y	N	N	NA	Y	N	CD	NA	NA	N	Good
Molfenter et al. (2012)	Y	Y	N	Y	Y	Y	Y	NA	Y	N	Y	NA	NR	Y	Good
Molloy et al. (2012)	Y	N	NR	Y	Y	N	N	NA	Y	N	Y	NA	NA	N	Fair
Moore (1995)	Y	N	NR	Y	Y	N	N	NA	Y	N	N	NA	NA	Y	Poor
Murphy et al. (2018)	Y	Y	CD	Y	Y	N	N	NA	Y	N	Y	NA	NA	N	Fair
Nelsen et al. (2013)	Y	Y	N	Y	CD	N	N	NA	Y	N	Y	NA	NA	N	Fair
O'Connor et al. (2015)	Y	Y	N	Y	Y	N	N	NA	Y	N	Y	NA	NA	Y	Fair
O'Connor et al. (2019)	Y	Y	N	Y	Y	Y	Y	NA	Y	N	Y	NA	N	Y	Good
Pakpour et al. (2014)	Y	Y	Y	Y	Y	Y	Y	NA	Y	N	Y	NA	Y	Y	Good
Peleg et al. (2017)	Y	Y	Y	Y	Y	Y	Y	NA	Y	N	Y	NA	Y	N	Good
Phillips et al. (2013)	Y	N	N	Y	Y	Y	Y	NA	Y	N	Y	NA	Y	N	Good
Phillips et al. (2016)	Y	N	N	Y	Y	N	N	NA	Y	N	Y	NA	NA	Y	Fair
Presseau et al. (2017)	Y	N	N	Y	Y	Y	Y	NA	Y	N	Y	NA	CD	N	Good
Putman (2004)	Y	N	N	Y	Y	N	N	NA	Y	N	Y	NA	NA	N	Fair
Quine et al. (2012)	Y	N	Y	Y	Y	Y	Y	NA	Y	N	Y	NA	N	N	Good
Scholz et al. (2012)	Y	N	N	Y	Y	N	N	NA	Y	N	Y	NA	NA	Y	Good
Schutte (2006)	Y	N	CD	Y	Y	Y	Y	NA	Y	N	Y	NA	CD	Y	Good
Stilley et al. (2010) A	Y	N	CD	CD	N	Y	Y	NA	Y	N	Y	NA	CD	N	Poor
Stilley et al. (2010) B	Y	N	CD	Y	N	Y	Y	NA	Y	N	Y	NA	CD	N	Fair
Stilley et al. (2010) C	Y	N	CD	Y	N	CD	CD	NA	Y	N	Y	NA	CD	N	Poor
Stoehr et al. (2008)	Y	Y	CD	Y	N	N	N	NA	Y	N	N	NA	NA	Y	Poor
Thames et al. (2011)	Y	N	CD	Y	Y	N	N	NA	Y	N	Y	NA	NA	Y	Fair
Waldrop-Valverde et al. (2006)	Y	N	CD	Y	Y	N	N	NA	Y	N	Y	NA	NA	N	Poor
Widjanarko et al. (2018)	N	Y	CD	Y	N	N	N	NA	N	N	N	NA	NA	N	Poor
Wolkovich (2017)	Y	N	CD	Y	Y	Y	Y	NA	Y	N	Y	NA	CD	CD	Fair

Note. * no full text available; Y = quality criteria met; N = quality criteria not met; NA = quality criteria not applicable; NR = quality criteria not reported; CD = quality criteria cannot be determined.

Criteria 1 = Was the research question or objective in this paper clearly stated?; Criteria 2 = Was the study population clearly specified and defined?; Criteria 3 = Was the participation rate of eligible persons at least 50%?; Criteria 4 = Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?; Criteria 5: Was a sample size justification, power description, or variance and effect estimates provided?; Criteria 6 = For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?; Criteria 7 = Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?; Criteria 8 = For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome?; Criteria 9 = Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?; Criteria 10 = Was the exposure(s) assessed more than once over time?; Criteria 11 = Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?; Criteria 12 = Were the outcome assessors blinded to the exposure status of participants?; Criteria 13 = Was loss to follow-up after baseline 20% or less?; Criteria 14 = Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?

Discussion

This is the first meta-analysis of studies that apply Temporal Self-Regulation Theory constructs to medication adherence across a range of illnesses. Three random-effects meta-analyses were conducted assessing the association between a Temporal Self-Regulation Theory construct (intention, behavioural prepotency, or self-regulatory capacity) and medication adherence. No studies tested or reported on the interactions between the theory variables and adherence, and therefore this analysis could not be conducted.

Temporal Self-Regulation Theory

The findings of the current meta-analysis provide support for the use and application of Temporal Self-Regulation Theory to medication adherence, albeit with small effect sizes ranging from 0.137 (self-regulatory capacity) to 0.302 (intention) (Cohen, 1988). The findings showed all three associations were significant, which supports Temporal Self-Regulation Theory (Hall & Fong, 2007). Intention had the strongest association with medication adherence behaviour, which is consistent with the theory and a previous meta-analysis assessing the predictive ability of intention in adherence behaviours (Hall & Fong, 2007; Rich et al., 2015). While this finding is not unsurprising, what is interesting about this finding is that the strength of the association is considered moderate ($r = .302$), which is not expected given intention is considered the most pertinent predictor of behaviour in various theories of behaviour change (Ajzen, 1991; Hall & Fong, 2007), and in a previous meta-analysis by McEachan et al. (2011) intention also had the strongest association with future health behaviour. As we were unable to test the multivariate relationships between the Temporal Self-Regulation Theory variables and

medication adherence, the association between intention and adherence may be moderated by other variables such as habit strength (Hall & Fong, 2007), which is predicted by Temporal Self-Regulation Theory. Due to the lack of research exploring these multivariate relationships in medication adherence, we suggest future research applies Temporal Self-Regulation Theory to medication adherence to better understand these relationships and interactions, or at the very least, assesses some of the moderating effects of behavioural prepotency and self-regulatory capacity on the intention-adherence relationship.

Regarding behavioural prepotency, the identified association with medication adherence was small-to-medium ($r = .282$) (Cohen, 1988). This finding supports the tenants of Temporal Self-Regulation Theory, as behavioural prepotency is hypothesised to significantly predict behaviour (Hall & Fong, 2007). This is an insightful finding as it not only supports Temporal Self-Regulation Theory, but there are currently no other meta-analyses in the literature that have assessed the pooled strength of the association between behavioural prepotency and medication adherence. However, a recent systematic review by Badawy et al. (2020) identified a strong association between habit strength and medication adherence in chronic disease in 11 studies. This finding is inconsistent with our current finding, even though nine of the studies included in the systematic review were included in our current meta-analysis. One possible reason for this was the inclusion of acute illnesses (e.g., those requiring a short dose of antibiotics) and when-needed medication (e.g., prophylactic asthma inhaler) in our meta-analysis. This may have weakened the behavioural prepotency and adherence relationship because

according to habit theory, a behaviour needs to be executed repetitively in response to the same environmental cues, in the same context (Gardner, 2015; Lally et al., 2010), which is unlikely for when-needed medications. Similarly, we also included studies that measured the association between cues to action and adherence. However, both of these variables were included in the moderator analysis, and both did not moderate the behavioural prepotency and adherence association, suggesting neither the type of illness/medication or measurement of cues affected the association. While both reviews combined the current literature to arrive at a conclusion, the Badawy et al. (2020) systematic review did not conduct any quantitative analysis of the associations but rather summarised the findings. Subsequently, there are no details outlining how the authors arrived at their conclusion that habit, and adherence are strongly associated given our pooled correlation of $r = .282$. Due to meta-analyses not evaluating or summarising the findings, but rather analysing them statistically (Ganeshkumar & Gopalakrishnan, 2013), we believe the conclusion we have arrived at is the strongest and least biased (Drucker et al., 2016). But more research is clearly needed.

Furthermore, of the 14 studies that measured behavioural prepotency only two studies measured cues to action (Cook et al., 2015; Widjanarko et al., 2018). Given there were no time restrictions (apart from up to November 2019) for the articles in this review, the lack of research exploring the relationship between cues and medication adherence is concerning. Previous research studies, particularly qualitative studies, have shown the importance of cues such as physical/visual cues, and contextual cues in aiding in medication adherence (Liddelow et al., 2020; Orr et al., 2007), but it seems as though the

role of cues are rarely quantitatively explored. Future research should consider conducting quantitative research to understand the influence cues have on adherence to medication, using measures such as the Cues to Action Scale (Booker & Mullan, 2013). If this shows strong associations, this can provide additional avenues for interventions.

Further support for the theory was identified in the significant relationship between self-regulatory capacity and medication adherence. However, it was the weakest association amongst the three constructs ($r = .137$) which suggests it may not be as important in medication adherence as intention or behavioural prepotency. This finding may be the result of many of the included studies measuring executive function as a whole, rather than specifically self-regulatory abilities such as managing impulses, emotions, and behaviours. Many of the tasks used to measure executive function in these studies (e.g., Trail Making Test B) measure cognitive processes that are not necessarily related to medication adherence, such as visual search and scanning, shifting, and psychomotor speed (Salthouse & Fristoe, 1995; Strauss et al., 2006; Sulaiman et al., 2017). Thus, the association identified between self-regulatory capacity and medication adherence may not be an accurate representation of the true association between the two variables. Similarly, of the five studies that measured self-control or self-regulation through self-report, only one study measured state-based (specific to medication) self-regulation whereas the others measured trait-based (general ability) self-regulation. All of the studies included in the intention and behavioural prepotency meta-analyses included state-based measures of intention, habit and cues and yielded stronger associations. It may be that because self-control and

self-regulation were mostly measured as a trait ability the association with adherence is weaker. Future research in this area should consider using measures that specifically measure a cognitive ability rather than overall executive function, as well as use state-based measures of self-regulatory capacity rather than trait-based to ensure more accurate and valid findings regarding the association between self-regulatory capacity and medication adherence.

Measuring Medication Adherence

In relation to this, moderator analysis showed that using a composite measure (i.e., subjective/self-report, and objective) of medication adherence when exploring the relationship between self-regulatory capacity and adherence is better than using a subjective measure (i.e., self-report) of adherence, alone. This finding is not unexpected and has been suggested by other researchers in the field (e.g., Lam & Fresco, 2015). However, using a multi-measure approach to measure medication adherence is not always feasible, such as when conducting survey-based research.

Specifically related to subjective measures of adherence, moderator analysis also showed that for the associations between behavioural prepotency and adherence, using subjective measures of behaviour rather than attitudes/beliefs-based subjective measures resulted in a significantly stronger association with adherence. This provides evidence for the continued use of subjective measures that actually measure behaviour, such as the Medication Adherence Report Scale (MARS-5), Morisky Medication Adherence Scale (MMAS-8) and the Timeline Follow-Back. However, only one of the studies in

the behavioural prepotency analysis used an attitudes/beliefs-based subjective measure so this finding needs to be interpreted with caution.

Practical Implications

The findings of this meta-analysis provide support for the continued exploration and study of the three Temporal Self-Regulation Theory constructs in medication adherence. Although half of the studies were cross-sectional in nature, many of the studies were still prospective or longitudinal in nature with sufficient time between baseline and follow-up to see predictive effects of the constructs on adherence. Nevertheless, future research using prospective designs is warranted given the strengths of this research design over purely cross-sectional designs (Setia, 2016). Findings showed that all three constructs were positively correlated with medication adherence, suggesting improvements in any one of the constructs could result in improvements in medication adherence. This lends itself to experimental research and interventions aimed at improving medication adherence to include components to increase intention, behavioural prepotency/habit strength or self-regulatory capacity. However, as the analysis of the interactions was unable to be conducted it is unknown exactly how improvements in one construct may influence the strength of another.

Strengths and Limitations

One of the main strengths of this meta-analysis is that multiple different databases were searched when locating studies. This was to ensure that all areas of health, medicine and psychology were accounted for. Similarly, the included articles were published between 1988 – 2019, therefore providing a comprehensive analysis and summary of the current literature. Another

strength of this review is the number of countries and illnesses that were represented in the analysis. Studies were conducted in both high- and low-income countries and assessed adherence to a range of diseases. This increases the generalisability of the findings of the review. However, our review is not without its limitations.

Firstly, there was substantial heterogeneity within all three meta-analyses, all of which were over 85% which is considered high according to Higgins et al. (2003). A degree of heterogeneity was expected due to including studies that focussed on different illness/medications and therefore a random-effects meta-analysis was used. However, a minimum of 85% heterogeneity suggests that the included studies are too different from one another. This made qualitative and quantitative synthesis and comparisons of the literature difficult. As the differences between illnesses/medications cannot be amended, we call for action to be made regarding the measurement of medication adherence in studies. There were over 30 different measures of medication adherence behaviour used throughout the 69 studies included in analysis. Whilst some measures did have their similarities (e.g., subjective, or objective measure), each measure was still different from the others. We suggest all future research, if feasible, consider using both subjective and objective measures of medication adherence rather than just one or the other, as well as ensuring the subjective measure of adherence used is a measure of actual behaviour. We suggest the use of the Medication Adherence Report Scale (Horne & Weinman, 1999) which is free to use, quick to complete and easy to understand, in combination with an electronic objective measure of adherence, such as the gold standard electronic objective measure, Medication Event

Monitoring Systems (MEMS®). If unable to use both in combination, we suggest using the one that is most feasible for the research design.

Secondly, the large majority of studies assessed adherence in chronic disease and not in acute diseases or infections that only require a short-term dose of medication such as antibiotics. Although some of the included studies were focussed on acute diseases, the applicability of the findings to these diseases and the medications used to treat them, are limited. Whilst it is important to ensure effective adherence to medications in chronic disease, given the recent global antibiotic/antimicrobial resistance epidemic (WHO, 2015) it is important that future research explores how to improve adherence to more short-term medication regimens.

Thirdly, many of the identified studies that were appropriate for inclusion did not contain the correct statistics for our meta-analysis. As a result, authors contact details were obtained and authors were contacted via email requesting these statistics. However, the response rate was poor with only 8 out of 33 (24.24% response rate) authors contacted responding to requests for additional information. As a result, many studies that would have made a meaningful contribution to the meta-analyses were forced to be excluded. As a result, the findings of this meta-analysis need to be interpreted with caution as it is not an accurate representation of all the literature in this area.

Conclusion

The current meta-analysis is the first to synthesise the associations between the Temporal Self-Regulation Theory constructs and medication

adherence. The findings provide support for the theory as well as the influence of each construct in medication adherence. All three constructs (intention, behavioural prepotency, and self-regulatory capacity) were weakly-to-moderately associated with medication adherence, despite a large amount of heterogeneity in the analyses, particularly in the measurement of adherence and the illness of interest. We suggest all future studies in this area consider the use of both subjective and objective measures of adherence, to ensure greater ease in the future synthesis of the literature. The interactions between the constructs were unable to be assessed due to lack of research, and thus future research should apply the theory to adherence to explore these interactions proposed by the theory. Future research should also consider experimental research that incorporates elements and techniques aimed at increasing one of the Temporal Self-Regulation Theory constructs, to thus possibly increase medication adherence.

Chapter 3: Understanding the Predictors of Medication Adherence: Applying Temporal Self-Regulation Theory

Introduction to Chapter 3

In the previous chapter I identified that there were significant associations between the three Temporal Self-Regulation Theory variables (Hall & Fong, 2007) and medication adherence. However, no studies had investigated the inter-relationships between the three constructs, as specifically proposed by the theory. Therefore, to do this and to assess the applicability of the theory to medication adherence, I applied Temporal Self-Regulation Theory (Hall & Fong, 2007) to adherence to prescription medications. Additional variables, such as side effects and medication regimen complexity, which have been identified as being potentially important covariates (George et al., 2004; Osterberg & Blaschke, 2005), were also included in the model to explore if the Temporal Self-Regulation Theory variables contributed to the prediction of adherence over and above these non-malleable constructs.

Furthermore, in the previous chapter I identified a moderating effect of the type of measure of medication adherence, suggesting the type of measurement used for adherence influenced the relationship between variables. Although I suggest the use of a composite measure (i.e., including both an objective and subjective measure of adherence) in future research, due to the online nature of the data collection this was not feasible. Subsequently I decided to include two freely available subjective self-report measures of medication adherence, the Medication Adherence Rating Scale (Thompson et al., 2000) which is typically applied to adherence to medications (particularly to anti-psychotics), and the

Timeline Follow-Back (Liddelow, Mullan, & Novoradovskaya, 2020; Sobell & Sobell, 1992), to explore and assess any differences in the overall findings or applicability of the theory. This was due to the previous chapter identifying differences in what medication adherence measures actually measure, with some measuring attitudes and beliefs, and the others measuring behaviour and as such, influencing the overall strength of relationships.

Published:

Liddelow, C., Mullan, B., & Boyes, M. (2020). Understanding the predictors of medication adherence: Applying Temporal Self-Regulation Theory. *Psychology and Health*. <https://doi.org/10.1080/08870446.2020.1788715>

Author	Contribution	I acknowledge that these represent my contribution to the above research output Signed:
Caitlin Liddelow	Development of research question, data collection, data management, data analysis, interpretation of results and discussion, manuscript preparation, reviewing and editing of drafts	
Barbara Mullan	Assisted with development of research question, interpretation, and manuscript preparation, reviewing and editing of drafts	
Mark Boyes	Assisted with development of research question, interpretation, and manuscript preparation, reviewing and editing of drafts	

Abstract

This study aimed to explore the applicability of Temporal Self-Regulation Theory (TST) in adherence to medication, using two self-report measures of behaviour. Recruited through TurkPrime, 191 US adults completed a two-part study. Temporal Self-Regulation Theory constructs of intention, behavioural prepotency (past behaviour, habit, cues), self-regulation (self-control, planning) with regimen complexity, and side effects were measured at time one. At time two, adherence behaviour over the previous week was measured using a revised Medication Adherence Rating Scale and an adapted Timeline Follow-Back. Constructs of Temporal Self-Regulation Theory accounted for 51.5% of variance in adherence as assessed by the rating scale. Past behaviour and cues were significant. Habit and planning moderated the intention-adherence relationship. Similarly, the Temporal Self-Regulation Theory constructs accounted for 20.6% of variance when measured by the Timeline Follow-Back. Intention, cues, and self-control were significant predictors. Interestingly, cues was the only common significant predictor. Temporal Self-Regulation Theory was partially supported, and the role of both rational and automatic factors was supported, however findings differed depending on the type of measure. Future developers of interventions may consider targeting cues to improve medication adherence. Future research also needs to further explore the role of intention, past behaviour, self-control, habit, and planning in medication adherence.

Introduction

Non-adherence to prescription medication is a global issue, impacting the individual, economy and health-care systems (Brown & Bussell, 2011). Medication adherence commonly refers to whether patients take their medication correctly as prescribed by their health-care professional (Ho et al., 2009) and whether they continue to take their medication. Approximately 30-50% of adults experiencing chronic illness do not take their medication as prescribed (Briesacher et al., 2008). Non-adherence to medication has shown to be associated with an increase in hospital visits, experiencing negative symptoms and risk of mortality (Ho et al., 2009). It is estimated 4% of all hospital admissions in North America, Asia, Europe and Australia are the direct result of medication non-adherence (Mongkhon et al., 2018). In the United States, non-adherence costs the economy approximately \$100-\$300 billion USD annually, through hospital admissions and medical interventions (Iuga & McGuire, 2014).

Medication-taking behaviours are complex. Over the past decade, much research has been conducted in efforts to improve rates of non-adherence, but no significant improvements have been seen (Zullig et al., 2018). Research has tended to focus on demographic predictors, such as sex, gender and ethnicity, which are not amenable to change (Alsabbagh et al., 2014; Manteuffel et al., 2014; Zhang & Baik, 2014). Furthermore, side effects of medication and the complexity of the medication regimen both negatively influence adherence rates, but are also not easily amendable (George et al., 2004; Osterberg & Blaschke, 2005). Exploring potentially modifiable predictors of adherence may be more useful to guide interventions. Thus, research investigating modifiable

factors influencing medication adherence, while controlling for non-malleable influences, is needed to both understand and change these behaviours.

Several theoretical perspectives have been applied to the study of medication adherence behaviours, however, the theory of planned behaviour (Ajzen, 1991) is the most widely used (McEachan et al., 2016; Rich et al., 2015). The theory of planned behaviour proposes intention is the strongest predictor of behaviour (Ajzen, 1991), but research in recent years has found an ‘intention-behaviour gap’ (Conner & Armitage, 1998; Sheeran, 2002), with the theory predicted only 9% of the variance in adherence behaviour (Rich et al., 2015). In attempts to bridge this gap in health behaviours, various psychological mechanisms have been included to extend the model, including habit and planning. Both have shown to moderate the intention-behaviour relationship (De Bruijn et al., 2012; Kothe et al., 2015), but have also shown to directly predict behaviour (Allom et al., 2013, 2016). It may be important to consider the role of all of these variables, in conjunction with one another, in the context of adherence (Sniehotta et al., 2014).

Temporal Self-Regulation Theory (Hall & Fong, 2007) incorporates both rational (e.g., intention) and automatic (e.g., habit) predictors of behaviour, attempting to bridge the intention-behaviour gap. It proposes in addition to intention, both behavioural prepotency and self-regulation influence behaviour and together they moderate the relationship between intention and behaviour (Hall & Fong, 2007). The theory has been applied to numerous health behaviours such as healthy and unhealthy eating (Evans et al., 2017), binge drinking (Black et al., 2017) and, supplement and vitamin use (Allom et al., 2018). It has yet to be applied to medication adherence, even though many

of its components have shown to be important in adherence, such as habit (Phillips et al., 2013), past behaviour (Molfenter et al., 2012), and self-regulation in the form of planning (Pakpour et al., 2014). Exploring medication adherence using Temporal Self-Regulation Theory may be an important step in identifying the potential relationships between important variables.

Behavioural prepotency is the automatic component of the model and refers to the likelihood of performing a behaviour based on the frequency of past behaviour, how habitual or automatic the behaviour is and how we respond to both internal and external cues (Allom et al., 2018; Booker & Mullan, 2013; P. A. Hall & Fong, 2007). Past behaviour has historically been proposed to be the most pertinent predictor of future behaviour (Ajzen, 2011). However, past behaviour alone is not an accurate measure of behavioural prepotency or automaticity such that a high frequency of past behaviour does not always mean the behaviour is habitual (Ouellette & Wood, 1998; Verplanken & Orbell, 2003). Therefore, Hall and Fong (2007) recommend all three constructs of behavioural prepotency be measured (i.e., past behaviour, habit, and cues). Furthermore, the cues related to medication adherence have not been extensively researched and has tended to only be explored as an intervention known as cue-dose training (involves patients identifying a contextual cue to help them remember to take their medication, such as brushing teeth), rather than as a predictor (e.g., Bosworth et al., 2011; Rosen et al., 2004). However, cues have shown to be important in other health behaviours, such as food intake (Neal et al., 2011) so may also be important in medication adherence.

A rational component, self-regulation, is a broad term which encompasses the trait and state cognitive ability to regulate and control emotions, thoughts and behaviour (Baumeister et al., 2007), all of which have been shown to be important in health behaviours (Allom et al., 2018; Allom & Mullan, 2014). In adherence, two facets of self-regulation, specifically self-control (the conscious ability to regulate emotions, behaviours, impulses and delay gratification) and planning (a self-regulatory process and mental strategy to make goal-directed actions easier to execute), have shown to be predictive of increased medication adherence (Gonzalez et al., 2016; Pakpour et al., 2014). The two most common ways of measuring self-regulation have been self-report measures and computer-based tasks (Duckworth & Kern, 2011). Self-report measures have shown to have higher convergent validity suggesting they are a better measure of self-regulation, as well as higher ease of use and implementation, compared to executive function tasks (Duckworth & Kern, 2011). Self-report measures of these constructs were therefore implemented in this research.

One of the issues in the research on medication adherence is the lack of reliable and valid self-report measures of adherence (Morisky & DiMatteo, 2011). The measurement of adherence to medication is complex with many measures providing varying results (Lam & Fresco, 2015; McRae-Clark et al., 2015). Many objective measures, such as MEMS bottle caps, are expensive to administer, not always feasible (e.g., online), time-consuming and are a burden on participants (Lam & Fresco, 2015; Stirratt et al., 2015), and therefore self-report measures tend to be the chosen method, even if they may not be as reliable or valid. Self-report measures are more flexible and cheaper, most

often free, while still presenting good reliability and validity. With the continued use of self-report measures in both research and clinical settings, it is important to explore and identify the better self-report behaviour measures in the literature, particularly the ones that actually measure behaviour.

One of the most widely used and freely available self-report questionnaires of medication adherence is the Medication Adherence Rating Scale (MARS; Thompson et al., 2000), which is the validated composite of two other measures, the drug attitude inventory (DAI) and the medication adherence questionnaire (MAQ). The Medication Adherence Rating Scale has shown good reliability, test-retest reliability, and validity through being significantly correlated with blood results (Thompson et al., 2000). However, some literature suggests attitudes towards medication do not correlate with actual adherence (Culig & Leppée, 2014; Fialko et al., 2008), therefore this measure of behaviour may be confounding the measurement of beliefs or attitudes towards medication with medication adherence behaviour. As a result, this poses potential issues with the reliability and validity of this measure as a measure of medication adherence behaviour.

In contrast, the Timeline Follow-Back (Sobell & Sobell, 1992) is an example of a self-report scale where participants must retrospectively estimate their behaviour and it can be suggested that this measure is a more accurate measure of medication adherence behaviour. This is due to the measure solely focussing on a re-count of behaviour/actions over a specified time period, rather than including attitudes towards medication in its measure of behaviour. The Timeline Follow-Back has been extensively used in the health behaviours, showing construct validity in an adolescent smoking sample (Lewis-Esquerre

et al., 2005), with blood alcohol levels (Francis et al., 2015), as well as accelerometer physical activity in college students (Panza et al., 2012). These two different types of self-report behaviour measures are yet to be explored or compared within a general medication adherence setting, with the MARS being extensively used to measure adherence to antipsychotic medication and other medications to treat schizophrenia and psychosis (Thompson et al., 2000). It is important to explore these measures such that appropriate decisions around measurement in future research can be made.

In light of previous research and the tenets of Temporal Self-Regulation Theory, this prospective two-part study aims to explore the constructs of Temporal Self-Regulation Theory as predictors of general medication adherence. Furthermore, we aim to explore the current self-report measurement issue by using two different types of self-report measures of behaviour. Gender and socioeconomic status will be included as covariates as they have been shown to influence adherence to medication (Alsabbagh et al., 2014; Manteuffel et al., 2014), as well as medication regimen complexity and medication side effects (George et al., 2004; Osterberg & Blaschke, 2005). Based on the assumptions of Temporal Self-Regulation Theory, it was hypothesised:

H1: Intention will predict a significant proportion of the variance in medication adherence using the two self-report measures of adherence behaviour (Medication Adherence Rating Scale and adapted Timeline Follow-Back).

H2: Both behavioural prepotency and self-regulation will account for additional variance in medication adherence.

H3: Behavioural prepotency is hypothesised to moderate the intention-behaviour relationship, such that the association between intention and adherence will be weaker at high levels of behavioural prepotency.

H4: Self-regulation will moderate the intention-behaviour relationship, such that the association between intention and adherence will be weaker at low levels of self-regulation.

Methods

Participants

Using G*Power, with a medium effect size ($f^2 = .15$), power $a = .80$, error probability of .05 and a total of 15 predictors, a minimum sample size of 139 was computed. Participants were recruited through the online Amazon crowdsourcing website TurkPrime (Litman et al., 2017). In part one participants were paid \$0.50 USD and \$1.50 USD for the completion of part two. All participants had to be mature minors (i.e., over the age of 16 years), understand the English language, and be taking regular prescription medication for an ongoing health concern. At baseline, 352 participants completed part one; however, after the deletion of duplicates and those with 30% or more missing data, the total number of participants at part one was 314. A total of 207 participants completed both parts of the study ($M_{age}=38.07$, 51.8% male, 71% identified as Caucasian, 85.5% earning up to \$87,000 annually, 94.3% insured).

Measures

Part one

Intention. This was measured using two statements (e.g., “I intend to adhere to my medication as prescribed, over the next week”) on a 7-point Likert scale ($1 = \textit{strongly disagree} - 7 = \textit{strongly agree}$) previously used in a study exploring medication adherence using the theory of planned behaviour (Liddelow, Mullan, & Novoradovskaya, 2020). Participants were asked to select the answer that best reflects their intention to adhere to their medication, with the mean of both items indicating higher intention. Internal consistency was excellent ($\alpha = .90$), according to the rules of thumb guided by Cronbach (1988) and Tavakol and Dennick (2011).

Behavioural Prepotency. This was measured using scales measuring three different aspects of the prepotency of medication adherence. The cues to action scale (Booker & Mullan, 2013) was used to measure the triggers of medication adherence using five subscales, namely physical, sensory, social, internal and emotional cues. Participants were asked, for example, “Are there any physical things in the environment which trigger you to take your medication?” ($1 = \textit{yes} - 2 = \textit{no}$), followed by a question related to frequency ($0 = \textit{never} - 7 = \textit{a few times a day}$) and a question related to how influential the triggers were at eliciting behaviour ($0 = \textit{not at all likely} - 6 = \textit{every time}$). If participants responded ‘No’ to the first question, they received a total score of zero for the subscale. If participants responded ‘Yes’ to the first question, scores on the frequency and influence questions were multiplied to give a score for that subscale. The mean of all five subscales was used as the overall score, with higher scores indicating participants experiencing more types of cues and these cues being more influential in behaviour.

The self-report behavioural automaticity index (Gardner et al., 2012; Verplanken & Orbell, 2003) was used to measure the automaticity of medication adherence. All questions started with “Ensuring I take my medication correctly is something....”, followed by an action “I do automatically”. Participants were asked to indicate how much they agree or disagree with four statements regarding their medication-taking behaviour, on a 7-point Likert scale (1 = *strongly disagree* - 7 = *strongly agree*). The mean of all answers was calculated, with higher scores indicating stronger automaticity. The index showed excellent reliability in this sample with a Cronbach’s alpha of $\alpha = .88$.

Past behaviour was measured using a single item related to the frequency of the behaviour (Gardner, Abraham, et al., 2012), taken from the self-report habit index (Verplanken & Orbell, 2003). Participants were asked to indicate how much they agree or disagree with the statement “Ensuring I take my medication correctly is something I do frequently”, on a 7-point Likert scale (1 = *strongly disagree* - 7 = *strongly agree*). A higher rating indicates a higher frequency of behaviour.

Self-Regulation. This was measured using two self-report measures of self-regulation. The brief self-control scale (Tangney et al., 2004) comprises of 13 statements about an individual’s self-control ability (e.g., “I am good at resisting temptation”) answered on a 5-point Likert scale (1 = *not at all like me* - 5 = *very much like me*). Participants were asked to select the answer that was most reflective of them, with higher scores indicating higher self-control and a Cronbach’s alpha of $\alpha = .87$. The second measure is the planning subscale from the self-regulation questionnaire (Brown et al., 1999). This subscale presents

10 trait statements related to the individual's ability to plan and set goals (e.g., "I have trouble making my mind up about things") on a 5-point Likert scale ($1 = \textit{strongly disagree} - 5 = \textit{strongly agree}$). Higher scores indicate a higher propensity to plan. The planning subscale has not been used separately to the self-regulation questionnaire, however, it showed good internal consistency in our study ($\alpha = .83$).

Medication Regimen Complexity. The complexity of the individual medication regimen was assessed using the 65-item medication regimen complexity index (George et al., 2004), which is the most widely used measure of regimen complexity (Hirsch et al., 2014). The measure consists of three sections: route, dose, and special instructions, with each answer having a different weighting, depending on the complexity. For example, the route of taking a tablet orally has a weighting of 1 whereas applying drops to the eyes has a weighting of 2 with a higher weighting indicating higher complexity/difficulty (see Appendix D). The score from each section was summed to create a final score. A higher score indicates a more complex medication regimen.

Side Effects. There is currently no valid measure of medication side effects, so three questions were created for this study, one of which was only used for sample descriptive purposes. Participants were instructed to select dichotomously whether they experienced side effects from any of their medication ($1 = \textit{no} - 2 = \textit{yes}$). Those who selected 'no' received a total score of 0 for the scale. Those who selected 'yes' were then asked whether they felt as though the side effects they experience influence their overall ability to adhere to their medication on a 5-point Likert scale ($1 = \textit{definitely yes} - 5 =$

definitely not). Participants response to this item was their final total score for the scale. Responses to this item were reverse coded such that a higher score now indicated a greater influence of side effects on adherence. Total scores ranged from 0 (no side effects) to 5 (side effects definitely influence adherence). For example, a final score of 1 would mean the participant experiences side effects but they definitely do not affect their adherence.

Part Two

Medication Adherence. Adherence over the previous week was assessed using two separate self-report scales. The first was a revised version of the Medication Adherence Rating Scale (Thompson et al., 2000) which is a self-report measure asking participants to answer dichotomously (yes/no) to 10 questions about their medication-taking behaviour. For example, "Are you careless at times about taking your medication?". A higher rating indicated better medication adherence. The measure has been very widely used in previous studies exploring medication adherence to antipsychotic medication, however, its use in other contexts is limited. Reliability was adequate in this sample ($\alpha = .69$), however, because it was originally developed to measure adherence to antipsychotic medication, factor analysis was used to see if all 10 items loaded adequately in the context of general medication adherence behaviour (see Appendix F). The internal consistency of the reduced seven-item measure was substantially improved ($\alpha = .77$).

The second measure was an adapted version of the Timeline Follow-Back (Sobell & Sobell, 1992), appropriate for the behaviour of medication adherence, based on the adapted Timeline Follow-Back created by Liddelow and colleagues (2020). The Timeline Follow-Back has also been used in

various other health domains such as alcohol consumption (Francis et al., 2015; Sobell & Sobell, 1992) and smoking (Lewis-Esquerre et al., 2005). This method allows participants to recall their previous week by prompting them to think about each individual day in calendar form. It instructs participants to enter the day and date, as well as any special events that may have occurred on this day, such as a birthday or an exam. Participants are then asked to indicate the number of times they took their medication on that day and whether or not they took it as prescribed. A daily score of 2 was given if all reported medications were taken on that day and taken as prescribed. A daily score of 1 was given if only the medications were taken, but not taken as prescribed. A daily score of 0 was given if participants did not take their medications and subsequently did not take it as prescribed. To ensure accurate scoring in relation to the different number of medications reportedly taken by participants, the regimen complexity reported by participants in part one was checked. A sum of scores for the entire week was calculated, with a higher score indicating better self-reported adherence. Scores could range from 0-14, with 14 indicating participants took all their medications that day as prescribed.

Procedure

Ethics approval was obtained from the University's Human Ethics Committee. Participants on TurkPrime self-selected if they wanted to participate but had to meet the inclusion criteria advertised for the study which included taking regular prescription medication for an ongoing health concern. The survey was available on TurkPrime from October to December 2018. As part of the survey, participants had to supply their worker ID, so an email could be sent to them via TurkPrime one week later asking them to complete part

two. All participants gave informed consent before completing measures. Part one asked participants to complete the measures relating to the Temporal Self-Regulation Theory, regimen complexity and side effects and was advertised in six blocks each for approximately 48 hours. Part two was a follow-up measure of their medication adherence behaviour over the previous week and was available for completion over 30 days.

Data Analysis

Missing values analysis was conducted on the data from the 207 participants and the data was found to be missing completely at random ($\chi^2(302) = 207.49, p = 1.000$). Missing data points were therefore imputed using expectation maximisation. Assumption testing was conducted on the data and several outliers were identified. The decision was made to remove outliers that were shown as being 'extreme' in SPSS (i.e. values more than three box lengths from either end) (Parke, 2013), leaving 191 participants completing both parts and subsequently used in analyses. Socioeconomic status was calculated as annual income (USD) and insurance status (insurance or no insurance). Participants with a higher annual income and had insurance were deemed to have a higher socioeconomic status than participants who did not have insurance or who had a lower annual income. Chi-square analysis and t-tests were used to determine any differences between completers and non-completers. There were significant differences between completers (participants who completed both parts, $N = 207$) and non-completers (participants who only completed part one, $N = 107$) such that completers had simpler regimens, better self-regulatory capacity and reported experiencing fewer environmental cues (see Appendix F). Descriptive statistics and bivariate

correlations on the unstandardised variables were conducted. Two hierarchical multiple regression analyses were then conducted to examine the prediction of medication adherence, as measured by the Medication Adherence Rating Scale and the Timeline Follow-Back. To minimise collinearity all predictors were standardised.

Age was added to the covariates as it was significantly positively correlated with adherence ($r = .233$, $p = .002$). For each model, covariates were entered in steps one (age, gender, and SES) and two (regimen and side effects), all Temporal Self-Regulation Theory variables (intention, habit, past behaviour, cues, self-control, and planning) were added at step three, and at step four each of the interactions (intention x past behaviour, intention x habit, intention x cues, intention x self-control and intention x planning) were entered. Significant interactions in the multivariate analysis were plotted and tested using simple slopes analysis (Aiken & West, 1991) to further explore the association.

Results

Means, standard deviations and correlations of all variables in the regression are displayed in Table 3.1. Medication adherence as measured by the revised Medication Adherence Rating Scale was positively correlated with the Temporal Self-Regulation Theory variables intention, habit, past behaviour, self-control, and planning. Timeline Follow-Back adherence was positively correlated with intention, self-control, and planning. Interestingly, cues were negatively correlated with both measures of adherence.

Predicting Adherence - Revised Medication Adherence Rating Scale

In the first step age, gender and SES collectively accounted for a significant 5.5% of the variance in medication adherence. Regimen complexity and side effects in step two accounted for an additional 13.8% of variance. In step three the Temporal Self-Regulation Theory variables were added and accounted for a significant 29.3% of variance. In step four, the five interaction variables were entered into the model and accounted for an accumulated 4% of the variance in adherence (see Appendix F). The final model of the regression predicted 52.5% of the variance in medication adherence $R^2 = .52$, $F(16, 163) = 11.282$, $p < .001$. Medication regimen complexity, side effects, past behaviour, cues, and the interaction terms intention x habit and intention x planning were all significant predictors in the final model (see Table 3.2).

The significant interactions (intention x habit, and intention x planning) were plotted and simple slopes analysis conducted to determine whether intention was related to medication adherence at high (1 SD above the mean), medium (mean) and low (1 SD below the mean) levels of habit, and planning (see Figure 3.1 and 3.2). Simple slopes analysis revealed slopes at both low ($B = .22$, $p = .310$) and mean ($B = -.28$, $p = .139$) levels of habit were non-significant. However, the slope was significant at high levels of habit ($B = -.78$, $p = .007$), meaning there is a negative association between intention and medication adherence at high levels of habit. Similarly, simple slopes analysis showed the slope was significant for low planning ($B = -.67$, $p = .021$), but non-significant for both mean planning ($B = -.28$, $p = .139$) and high planning ($B = .23$, $p = .480$), meaning there is a negative association between intention and medication adherence at low levels of planning.

Table 3.1*Means, Standard Deviations and Correlations Between Variables*

	<i>M</i>	<i>SD</i>	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.
1.Age	38.83	11.61	.16*	.01	-.03	-.05	.27**	.11	.06	-.20*	.30**	.32**	.23**	.11
2.Gender	-	-		-.33**	.00	.17*	.21**	.15*	-.06	-.08	.25**	.12	.01	-.08
3.SES	-	-			.04	-.21**	-.05	-.03	.15*	-.05	-.05	.12	.02	.05
4.Regimen	4.23	2.60				.00	-.01	.15*	.09	.21**	.06	.07	-.17*	-.00
5.Side Effects	1.04	1.56					-.10	-.02	-.12	.35**	-.27**	-.22**	-.36**	-.12
6.Intention	6.26	0.93						.52**	.24**	-.17*	.37**	.33**	.30*	.22**
7.Past Behaviour	5.79	1.24							.44**	-.00	.23**	.24**	.31**	.08
8.Habit	4.92	1.49								.02	.19**	.19**	.21**	.10
9.Cues	20.32	30.16									-.30**	-.31**	-.51**	-.24**
10.Self-Control	44.95	10.11										.71**	.43**	.29**
11. Planning	31.33	6.47											.39**	.19**
12. MARS Adherence	4.88	2.09												.40**
13.TLFB Adherence	11.67	3.77												

Note: SES=socioeconomic status, * $p < .05$, ** $p < .01$

Predicting Adherence - Adapted Timeline Follow-Back

Age, gender, and SES accounted for a non-significant 2.8% of the variance in medication adherence. Regimen and side effects in step two accounted for a non-significant 1.2% of variance. At step three all Temporal Self-Regulation Theory variables were entered and accounted for a significant 12.4% of variance. At step four, the five interaction terms were entered and accounted for a non-significant 4.2% of variance, with no interactions being significant predictors (see Appendix F). The final model (see Table 3.3) accounted for a significant 20.6% of the variance in adherence, $R^2 = .21$, $F(16, 163) = 2.641$, $p = .001$. Gender, intention, cues, and self-control were significant predictors in the final model.

Table 3.2*Final Regression Model Using the Revised Seven-item Medication Adherence**Rating Scale*

	Variable	B [95% CI]	β	sr^2	p-value	R^2	ΔR^2	F	$\Delta F (df1, df2)$
Step 4					.000**	.525	.479	11.28	2.725 (16, 163)
	Age	.175 [-.077, .427]	.081	.01	.173				
	Gender	-.404 [-.928, .120]	-.096	.01	.130				
	SES	-.148 [-.393, .098]	-.071	.00	.236				
	Regimen	-.918 [-1.499, -.338]	-.180	.02	.002*				
	Side Effects	-.273 [-.531, -.015]	-.129	.01	.038*				
	Intention	-.197 [-.594, .200]	-.081	.00	.329				
	Past Behaviour	.615 [.309, .921]	.279	.05	.000**				
	Habit	.219 [-.060, .498]	.111	.01	.123				
	Cues to Action	-1.014 [-1.344, -.683]	-.394	.11	.000**				
	Self-Control	.424 [.016, .832]	.201	.01	.042				
	Planning	.052 [-.309, .414]	.025	.00	.775				
	IntentionXPB	.062 [-.207, .332]	.033	.00	.647				
	IntentionXHabit	-.487 [-.811, -.163]	-.231	.03	.003*				
	IntentionXCues	.017 [-.381, .414]	.005	.00	.934				
	IntentionXSC	-.051 [-.525, .423]	-.019	.00	.832				
	IntentionXPlanning	.435 [.012, .858]	.168	.01	.044*				

Note: SES=socioeconomic status, PB=past behaviour, SC=self-control. Significant steps and predictors are shown in bold. * $p < .05$ ** $p < .01$

Table 3.3*Final Regression Model Using the Adapted Timeline Follow-Back*

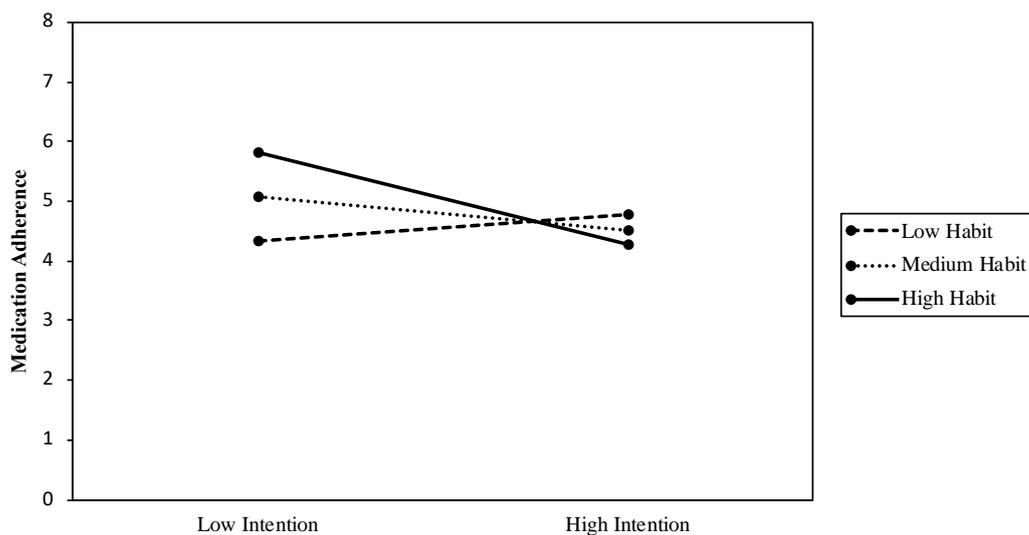
Variable	<i>B</i> [95% CI]	β	<i>sr</i> ²	<i>p</i> -value	<i>R</i> ²	ΔR^2	<i>F</i>	ΔF (<i>df</i> 1, <i>df</i> 2)
Step 4				.001**	.206	.128	2.64	1.727 (5, 163)
Age	.134 [-.446, .714]	.035	.00	.650				
Gender	-1.687 [-2.892, -.481]	-.225	.04	.006**				
SES	-.070 [-.634, .494]	-.019	.00	.807				
Regimen	.534 [-.802, 1.869]	.059	.00	.431				
Side Effects	.137 [-.457, .731]	.036	.00	.650				
Intention	1.214 [.301, 2.127]	.282	.03	.008**				
Past Behaviour	.001 [-.702, .705]	.000	.00	.997				
Habit	-.096 [-.738, .546]	-.027	.00	.768				
Cues to Action	-.825 [-1.584, -.066]	-.180	.02	.033*				
Self-Control	.996 [.057, 1.935]	.265	.02	.038*				
Planning	-.555 [-1.386, .275]	-.149	.01	.189				
IntentionXPB	.427 [-.192, 1.046]	.127	.01	.175				
IntentionXHabit	.332 [-.413, 1.078]	.088	.00	.380				
IntentionXCues	.682 [-.232, 1.596]	.119	.01	.143				
IntentionXSC	.241 [-.850, 1.332]	.050	.00	.664				
IntentionXPlanning	-.016 [-.988, .957]	-.003	.00	.975				

Note: SES=socioeconomic status. Significant steps and predictors are shown in bold.

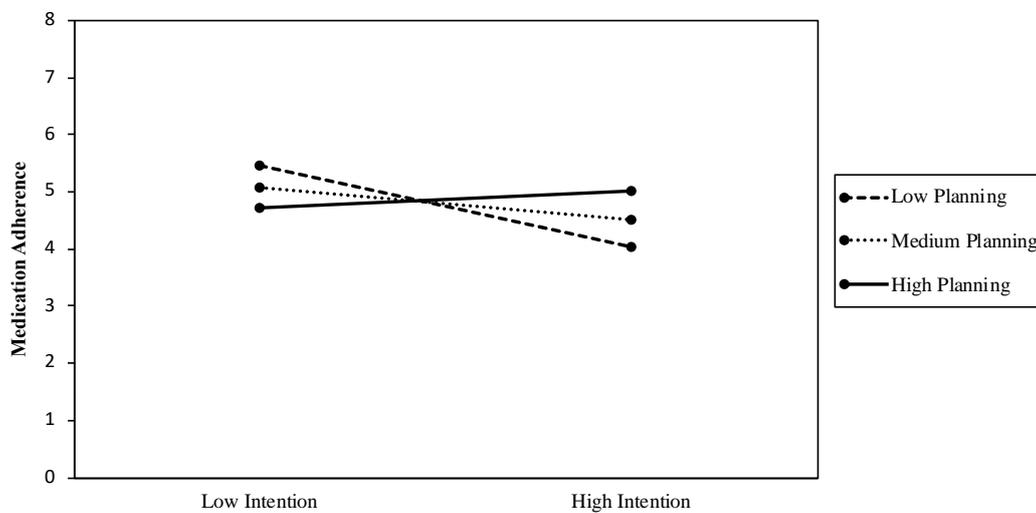
p*<.05 *p*<.01

Figure 3.1

Simple Slopes Analysis Showing the Relationship Between Intention and Habit on Medication Adherence

**Figure 3.2**

Simple Slopes Analysis Showing the Relationship Between Intention and Planning on Medication Adherence



Discussion

This study aimed to explore the utility of Temporal Self-Regulation Theory in predicting medication adherence. When using the revised seven-item Medication Adherence Rating Scale, the final model explained more than 50% of the variance in medication adherence, which is larger than the amount accounted for in other behaviours when using Temporal Self-Regulation Theory (Allom et al., 2018; Evans et al., 2017). Past behaviour and cues showed to directly affect adherence. Habit moderated the relationship between intention and medication adherence, specifically, there was a negative association between intention and adherence but only at high levels of habit, which is consistent with habit theory (Danner et al., 2008; Hall & Fong, 2007; Verplanken & Wood, 2006). Similarly, planning moderated the association between intention and medication adherence. Specifically, there was a negative association between intention and adherence but only at low levels of planning. This is also consistent with theory and expectations that suggests intention is not enough to execute a behaviour and goal-directed plans are needed to ensure behaviour is enacted (Sheeran et al., 2005). Specifically, in individuals with high planning, intentions are more closely related to behaviour (Wiedemann et al., 2009).

When using the adapted Timeline Follow-Back, the final model predicted substantially less variance in adherence (20.6%) with only intention, cues and self-control being significant. No moderation effects were present when using this measure. Results suggest that medication adherence is predicted by both rational (intention, past behaviour, self-control, planning) and automatic predictors (cues, habit). However, only cues were a significant

predictor of medication adherence across both measures of behaviour. The findings of both measures, their conclusions and the overall conclusions related to the utility of Temporal Self-Regulation Theory in predicting medication adherence, and the findings of the self-report measures of adherence, are discussed in more detail below.

Using the rating scale, intention was not significant but when using the Timeline Follow-Back intention was significant in the final model and accounted for the most unique variance. These mixed findings are not uncommon (see Collins & Mullan, 2011; McEachan et al., 2011) and provide further support that rational processes like intention, are not always the most pertinent predictors of behaviour. One explanation for this may be for protective health behaviours, such as taking medication (Harris & Guten, 1979), there is temporal uncertainty because the behaviour is distally beneficial, therefore de-motivating people to enact the behaviour even when intention is strong (Collins & Mullan, 2011).

Past behaviour was a significant predictor of adherence using the rating scale but was not significant in the Timeline Follow-Back. This finding is inconsistent with literature suggesting past behaviour is the best predictor of future behaviour (Ouellette & Wood, 1998) and suggests other behavioural prepotency variables may be more important. Cues was the strongest predictor of adherence when using the rating scale and was also a significant predictor using the Timeline Follow-Back. However, the presence of cues was expected to improve behaviour execution (Booker & Mullan, 2013; Hall & Fong, 2007); but in our study, the presence of fewer cues was more predictive of behaviour. This may be because taking medication is often linked to a time of day (e.g.,

morning or evening) or a specific symptom (e.g., difficulty breathing), compared to other behaviours such as snacking which is triggered by multiple cues (Grenard et al., 2013). Future research may benefit from exploring the potential for this behaviour to be 'hooked' to a single cue to elicit stronger adherence (Judah et al., 2013).

Also consistent with Temporal Self-Regulation Theory and previous research is the finding that self-regulation, particularly self-control, was directly predictive of medication adherence (Collins & Mullan, 2011; Insel et al., 2006; Sandberg & Conner, 2008). This is consistent with literature that has shown self-regulation is important in distally beneficial behaviours that do not yield an immediate reward (Hofmann et al., 2012), such as taking many medications. Engaging in distally beneficial behaviours are perceived as more difficult, therefore requiring a higher self-regulatory capacity, than engaging in an immediately rewarding behaviour, such as snacking (Collins & Mullan, 2011; Hall & Fong, 2007; Mullan & Novoradovskaya, 2018). However, consistent with this our findings indicate that at low levels of planning ability, intention was negatively associated with adherence. This may indicate that rational processes become less important when habit is strong, which is consistent with previous research (Verplanken & Wood, 2006).

Past behaviour and cues are both key constructs in the formation of a habit (Judah et al., 2013; Lally et al., 2010). In our data, both past behaviour and cues appear to be independently associated with adherence. This may indicate that adherence is not yet fully habitual in this sample, and this is supported by participants reporting that their adherence is not yet fully automatic ($M = 5.78$). The development of automaticity for complex

behaviours, like taking multiple medications at different times, may take longer to reach an overall lower level of automaticity than for a simple behaviour (Durand et al., 2018). It has also been questioned whether complex behaviours can truly become habitual as they involve numerous subsets of actions (Hagger, 2019; Phillips, 2019).

Practical Applications

First, both measures of adherence differ significantly in how adherence is conceptualised. The Medication Adherence Report Scale can be considered more of an attitude and beliefs scale rather than a behaviour scale (Nguyen et al., 2014). It appears that together, the Temporal Self-Regulation Theory variables account for more variance in an outcome measure that taps into attitudes/beliefs regarding adherence, rather than actual adherence behaviour over a given time frame. Similarly, some literature suggests attitudes towards medication do not correlate with actual adherence (Culig & Leppée, 2014; Fialko et al., 2008), therefore posing potential issues with its reliability as a measure of medication adherence behaviour. In contrast, the Timeline Follow-Back is a non-specific adherence measure but is a more accurate measure of behaviour as it specifically asks for the behaviour to be re-called and does not assess beliefs and attitudes. The accuracy of this measure has been shown in previous studies looking at smoking, alcohol consumption and physical activity (Francis et al., 2015; Lewis-Esquerre et al., 2005; Panza et al., 2012; Sobell & Sobell, 1992). Even though less variance was accounted for when using the Timeline Follow-Back, we suggest it may be more useful when actually interested in predicting behaviour rather than attitudes. Our results show that using two different self-report measures of behaviour result in different

findings. This adds to the adherence literature by identifying: 1) self-report measures of behaviour that confounds measures of attitudes/beliefs with adherence account for more variance in behaviour, but these attitudes may not be measuring adherence behaviour, 2) theoretical models of behaviour are better at predicting attitudes/beliefs related to medication adherence compared to actual behaviour and; 3) adherence behaviour is not something that is easily measured accurately through self-report and researchers need to consider which particular aspect of adherence they want to measure when selecting measures of adherence behaviour. If they are interested in actual behaviour, a retrospective measure like the Timeline Follow-Back is a better measure of adherence compared to the MARS which confounds attitudes/beliefs with adherence. Bearing these measurement considerations in mind and their differing results, the only predictor that was significant when using both measures was cues. This suggests that cues may be the most suitable target for psychosocial interventions aimed at improving adherence. Current interventions for improving adherence tend to be complex such that they aim to improve or target several different variables at one time (Nieuwlaat et al., 2014). Future research may consider targeting a specific type of cue (i.e., physical) to ensure interventions are simple and targeted. Behaviour change techniques, such as if-then statements in the form of implementation intentions or action planning, may be useful for enhancing the role of physical cues in improving medication adherence (Michie et al., 2008). These behaviour change techniques have also shown to improve promote automaticity (Gollwitzer, 1999; Michie et al., 2008).

Future research could also consider further exploring the role of past behaviour, intention, and self-control (which were all significant predictors when using either of the measures) and habit and planning (two moderating predictors). As our findings are very initial, they need to be replicated and the two measures of adherence need to be cross validated with objective measures of adherence. While observational studies like ours provide useful information on the associations between the theory and adherence to medication the observational nature precludes any directions of these associations and if they are causal. Therefore, while replication of our study is needed, employing experimental designs where participants are randomised to conditions and one of the key variables of Temporal Self-Regulation Theory (e.g., habit) is manipulated, may help to show causation and if these variables are linked to medication adherence.

Limitations

This research is not without its limitations. Firstly, our research experienced a high rate of attrition (41.16%), potentially due to the timing of the questionnaire being available on TurkPrime during a busy holiday period for North American residents (e.g., Halloween, Thanksgiving, Christmas). Participants that completed both parts had simpler regimens and therefore the results should be interpreted with this in mind, as the findings may not be generalisable to more complex medication regimens. Further, online crowdsourcing platforms such as TurkPrime come with their own validity issues such as participant inattentiveness and selection biases (Cheung et al., 2017). Data that was incomplete or presented obvious patterns of responses, such as placing the number 1 in each box of the Timeline Follow-Back even

where writing was requested, were excluded. TurkPrime also has options in place which allow for the identification of duplicate IP addresses, and this was utilised in this study. With regards to measures, it is possible that the measure of cues and side effects conflated the presence of both cues and side effects with how important these are in their adherence. Future research should consider disentangling these two aspects of cues and side effects. In addition, self-report measures are not without their limitations like reporting biases and social biases (Stirratt et al., 2015). Even though this study used two different types of self-report, biases may have still been present, and therefore results should be interpreted with this in mind. Although they have their limitations, self-report measures were the optimal choice for this study due to its online format and the flexibility and ease of such measures (Stirratt et al., 2015). The use of objective adherence measures, such as MEMS or electronic drug monitoring (EDM), was not feasible using TurkPrime. Further, as per habit theory (Gardner et al., 2011), habitual behaviours are said to be difficult to remember when and where they were executed. Therefore, although we suggest the use of the Timeline Follow-Back for future research in this area, it needs to be acknowledged that if medication adherence is truly habitual, this measure may not be accurate in determining true adherence as it relies on memory. Finally, the measure of past behaviour was a single item which can be unreliable or influenced by measurement errors, however, research shows that the use of more than one item to measure past behaviour is still significantly equally predictive (see Allom et al., 2013; Norman, Conner, & Bell, 2000; Norman & Conner, 2006).

Conclusion

Notwithstanding limitations, this study is the first to use two different measures of behaviour to predict medication adherence based on Temporal Self-Regulation Theory. The theory was partially supported in the prediction of medication adherence. Our findings when using both measures of adherence suggest the role of both rational and automatic factors in adherence, however, the only common significant predictor across both measures was cues, which is an automatic factor. We suggest interventions tailored to improve adherence consider targeting the role of cues, perhaps even a specific type of cue (e.g., physical). Findings from this study also highlight the importance of selecting appropriate measures of adherence behaviour in future research, such that if researchers want to measure adherence behaviour, rather than attitudes/beliefs confounded with adherence, we believe the Timeline Follow-Back is the better measure of behaviour and should be used in future research both in general adherence and when further testing the utility of Temporal Self-Regulation Theory in medication adherence.

Chapter 4: A Qualitative Application of Temporal Self-Regulation Theory to Understand Adherence to Simple and Complex Medication Regimens

Introduction to Chapter 4

In the previous chapter I identified that Temporal Self-Regulation Theory (Hall & Fong, 2007) was able to be successfully applied to medication adherence using a quantitative research design, with many of the theories' constructs identified as being important, particularly that of cues. This current chapter complements the previous chapter by further testing the theory, using in-depth qualitative interviews. Additionally, I sought to understand the experience of individuals engaging with both simple and complex medication regimens to explore whether the importance of constructs within the theory differ depending on the complexity of the regimen, because medication regimen complexity was controlled for in the previous studies. Similarly, previous research has shown differences in adherence due to the complexity of the regimen (George et al., 2004).

Published:

Liddelow, C., Mullan, B., Boyes, M. & McBride, H. (2020). A qualitative application of Temporal Self-Regulation Theory to understand adherence to simple and complex medication regimens. *Healthcare*, 8(4), 487.

<https://doi.org/10.3390/healthcare8040487>

Author	Contribution	I acknowledge that these represent my contribution to the above research output Signed:
Caitlin Liddelow	Development of research question, data collection, data management, data analysis, interpretation of results and discussion, manuscript preparation, reviewing and editing of drafts	
Barbara Mullan	Assisted with development of research question, interpretation, and manuscript preparation, reviewing and editing of drafts	
Mark Boyes	Assisted with development of research question, interpretation, and manuscript preparation, reviewing and editing of drafts	
Hannah McBride	Assisted with data analysis, interpretation of results, and manuscript preparation, reviewing of drafts	

Abstract

Medication adherence is a global health concern, and variables of Temporal Self-Regulation Theory (TST) have been shown to be important in improving adherence. This qualitative study aims to explore how Temporal Self-Regulation Theory can help explain medication adherence in people's daily lives, and whether there are differences in the adherence to simple and complex medication regimens. Twenty-nine participants from Australia engaged in semi-structured interviews based on Temporal Self-Regulation Theory (intention, behavioural prepotency, self-regulation), and other variables important to adherence. Interviews were analysed using thematic analysis. Six themes were identified (Routines, External Supports, Cost, Sense of Agency, Adverse Outcomes, and Weighing Up Pros and Cons), with partial support for Temporal Self-Regulation Theory (specifically intention, past behaviour, cues, and planning). Four themes not related to Temporal Self-Regulation Theory were also identified. Individuals with more complex medication regimens spoke of the importance of routines, planning, and knowledge-seeking, whereas those with simpler regimens spoke of the importance of visual cues. Temporal Self-Regulation Theory may be useful for identifying some variables important in medication adherence; however, additional factors were also identified. For simple regimens, future research should focus on the manipulation of visual cues. For complex regimens, health professionals should consider using interventions (e.g., medication management apps) that assist in the planning and promoting of medication, and treatment routines.

Introduction

In 2003, the World Health Organization (WHO) declared medication non-adherence as a worldwide issue of striking magnitude, which should be a priority for policymakers and health care providers (De Geest & Sabaté, 2003). Despite this, medication adherence remains a global health concern (Clyne et al., 2016). It is estimated that in developed countries, approximately 50% of adults with a chronic illness do not adhere to their medication regimens (Van Dulmen et al., 2007), with this number expected to be even lower for preventative medications such as the oral contraceptive pill, which do not provide instant symptom relief (Walker et al., 2006). Poor medication adherence increases the likelihood of experiencing adverse medical events, worsening of condition symptoms, increased comorbidity, higher health care costs, and in some instances, higher risk of mortality (Chisholm-Burns & Spivey, 2012). Similarly, medication non-adherence creates an economic burden, costing approximately USD 100–300 billion in the United States alone (Iuga & McGuire, 2014). With an increase in the number of co-morbid chronic diseases in adults, particularly young adults (Bonnie et al., 2015), including diabetes, hypertension, mental health disorders, Crohn's disease and arthritis (Australian Institute of Health and Welfare, 2007, 2012, 2019) it is important set up healthy and effective adherence patterns in young adulthood. The transition to adulthood is a difficult time for many, and a time where many begin to take control over their own health, however this population tends to be underrepresented in the adherence literature (Conn, Ruppap, et al., 2016; Shaw & Amico, 2016), with most research recruiting older adults.

There is a large body of scientific literature investigating medication adherence, or lack of adherence, using quantitative research methods. Many of these existing quantitative studies have employed the use of health psychology theories to explain non-adherence (Holmes et al., 2014), and to guide intervention creation in attempts to improve the behaviour (Michie & Johnston, 2012). In attempting to understand medication adherence, these quantitative studies have identified the role of important mechanisms such as self-efficacy, perceived barriers, perceived susceptibility, necessity beliefs, and concerns about medication (Holmes et al., 2014). Many of the theories have also been extended in attempts to negate weak relationships between variables (i.e., intention and behaviour in the theory of planned behaviour) (Liddelow, Mullan, & Novoradovskaya, 2020) or to explore the influence of non-psychosocial variables in medication adherence (i.e., side effects) (Liddelow, Mullan, & Boyes, 2020b). However, whilst these variables may be important for predicting adherence to various types of medications, it is not known which variables are more or less influential in predicting adherence to regimens of varying complexities. Complex medication regimens are commonly defined as taking at least five medications at one time (Muir et al., 2001).

Temporal Self-Regulation Theory (TST) (Hall & Fong, 2007) is a more comprehensive theory of behaviour change that incorporates dual processes (e.g., rational and automatic processes) in the prediction of behaviour. The theory extends from the primary premise of the theory of planned behaviour which suggests that intention is the most proximal predictor of behaviour (Ajzen, 1991) by incorporating additional processes, i.e., self-regulatory capacity (rational processes) and behavioural prepotency (automatic

processes). Rational or conscious processes are those under volitional control, such as intention and some self-regulatory processes like planning, goal-setting and self-efficacy (Schwarzer, 2008). Automatic or unconscious processes (i.e., habit) operate without conscious awareness and tend to be executed without thought (Wood & Runger, 2016). The theory proposes that intention, behavioural prepotency, and self-regulatory capacity all directly predict behaviour. In addition, both behavioural prepotency and self-regulatory capacity are proposed to moderate the intention–behaviour relationship (Hall & Fong, 2007).

Although Temporal Self-Regulation Theory has been quantitatively applied to various health behaviours (Allom et al., 2018; Evans et al., 2017; Moran & Mullan, n.d.) it has only been applied to medication adherence in one study (Liddelow, Mullan, & Boyes, 2020b). In this study, the theory predicted approximately 50% of the variance in adherence to a range of medication types and regimen complexities, with both rational (intention, planning and self-control) and automatic (habit and cues) processes being important. However, this study did not individually investigate the predictors of adherence to simple or complex regimens. Certain variables in Temporal Self-Regulation Theory may be more important in simple regimens, rather than complex regimens, and vice versa. For instance, habit may be more predictive of adherence to a simple regimen, as taking a single medication at the same time every day is likely to become more habitual, and the repetition of a single action within the same context is an optimum environment for habits to form (Wood & Runger, 2016). Similarly, more complex medication regimens have been associated with decreased adherence (Ayele et al., 2019). Thus, having a greater understanding

of the modifiable predictors that may be associated with increased adherence to these complex regimens is important, not only for researchers tailoring interventions, but also general practitioners and pharmacists. One way to go about this is through the use of qualitative research methods, as quantitative explorations of healthy psychology theories can only tell us what variables may be important in a behaviour but lack the “why”. Qualitative research also allows for the identification of additional variables that may not be accounted for in the theory and may be capable at predicting additional variance when tested quantitatively. Furthermore, qualitative research is important in medication adherence research as it allows both researchers and clinicians to further understand medication adherence, or non-adherence, from the patient’s point of view, rather than just their responses to self-report measures, which may be biased (McHorney, 2016).

By focusing research on the modifiable psychological variables associated with adherence to different medication regimen complexities, interventions aimed at increasing adherence to various regimen complexities can be tailored. In addition, by having a further understanding of the influence of the variables that may not be modifiable or accounted for in health psychology theories (e.g. side- effects), findings regarding these can be communicated with clinicians who can then provide their patients with ways of navigating and living with such effects, or be considered when designing interventions to improve adherence (Heath et al., 2015).

The Current Study

To guide this qualitative research study, the overarching research questions “what variables from Temporal Self-Regulation Theory are

important in adhering to different medication regimens, specifically simple and more complex regimens?” and “are there any additional variables, not included in the theory, that are important in effectively adhering to these different regimens?” were explored. The overarching aim was to explore how temporal self-regulation can help explain medication adherence in people’s daily lives, and whether the theory explains different patterns of behaviour in the adherence to simple and complex medication regimens. An inductive and deductive qualitative approach was used to ensure the possibility of identifying other additional variables that are important in adherence, and that are not accounted for in the theory. As Temporal Self-Regulation Theory only accounts for a moderate amount of variance, the identification of additional influences is just as important.

Methods

Participants

Participants were recruited through the University participant pool for undergraduate students and received course credit to thank them for their time. All participants were required to be over the age of 16 years and be taking regular prescription medication for an ongoing health concern.

Interview Schedule

A semi-structured interview schedule (see Appendix K) was developed for this study. The interview questions were based on the Temporal Self-Regulation Theory constructs—intention, habit, past behaviour, and self-regulatory capacity, and also included questions related to their experience of

side effects, current regimen, and support. All questions were open-ended and had several prompts associated with them to continue the discussion.

Procedure

Ethical approval for this study was obtained from the University's Human Research Ethics Committee (HRE2017-0173). Participants provided consent by checking a box in Qualtrics, completed a demographic questionnaire, and were invited to attend a face-to-face interview. Interviews lasted between 30 minutes to one hour and 15 minutes and were conducted until the interviewees no longer presented or discussed new information. Some interviewees were not as open about their experiences as others, and thus their interviews did not last as long despite attempts to delve deeper. All interviews were transcribed verbatim by an independent transcriber not associated with the study. After transcription, all identifying information was removed.

Data Analysis

Thematic analysis (Braun & Clarke, 2006) taking both a deductive and inductive approach, otherwise known as a hybrid approach (Swain, 2018), was applied to analyse the data through coding and the identifying of prominent patterns or themes. A hybrid approach to thematic analysis means that the theory of focus, in this case Temporal Self-regulation Theory, is both a precursor to, and an outcome of the analysis (Swain, 2018). All analysis was conducted by hand by two researchers. Each transcript was read through by both researchers to aid familiarisation. One researcher read each transcript line-by-line, interpreting analytic codes. The second researcher then further refined these codes into latent codes (preliminary themes). Both researchers met many times to further refine the latent codes into themes and subthemes to capture

the underlying ideas present in the data. This process was conducted until no further themes could be identified (Braun & Clarke, 2019; Creswell, 1998). The identified themes were checked by two additional researchers for review and feedback to strengthen the trustworthiness and dependability of the findings.

Quality Procedures

To ensure quality and rigor, each participant was sent a transcribed version of their interview for member checking (Birt et al., 2016), to ensure accuracy of the transcribed data to the participants' experiences and views (Lincoln & Guba, 1985). In addition, investigator triangulation through the use of two data analysts and two additional researchers checking the themes and associated codes and quotes, was used to reduce potential researcher subjectivity and bias in the interpretations and analysis of the data, and subsequently increases the trustworthiness of the study and findings (Lincoln & Guba, 1985; Turner & Turner, 2009). Any discrepancies or disagreements in analysis were verbally discussed and resolved. Throughout the analysis process, the researchers kept notes related to any broader concepts or ideas that seemed to underly the themes.

Findings

Participants

A total of 29 participants were interviewed, with the average number of participants in similar research being 33 participants (range = 7–98) (Kelly et al., 2014). Of these, 4 identified as male and 25 identified as female with ages ranging from 18 to 52 years ($M = 20.16$ years). Participants reported having

between one and five medications in their regimen. Regimens included a range of medication forms (i.e., tablets, injections, and inhalations), dosages (i.e., once daily, when needed, every other day) and a variety of health issues (e.g., acne/skin problems, depression, polycystic ovary syndrome/endometriosis, asthma, diabetes, obsessive-compulsive disorder, and anxiety).

Themes

Routines

The theme “Routines” describes participants’ process of purposefully implementing plans to assist in them maintaining their medication regimens in a consistent and routinised way. These routines appeared to be characterised by participants consciously putting plans into place, and the use of cues like setting an alarm or putting their medication in an easily visible location. Within this sample, this deliberate routinisation appeared to be more salient for more complex regimens (i.e., those managing a regimen of three to five different medications). For instance, one participant with a complex regimen commented:

Yeah just because I take it in the morning, so then like it’s easy just to take two at the same time (Participant 22, p. 4).

Here, the participant appeared to highlight that a simple routine, taking all medications at one time, was convenient and assisted in effective adherence. Furthermore, participants noted that significant changes to their routine appeared to impact their adherence in that they were more inclined to miss their medication after a routine change. For example, one participant, whose regimen changed from taking all medications in the morning to taking one of them at night, said:

So when I added my, when I used to take the (medication) in the morning, that was the easiest, just to remember to take them both together. But now the other one is at night. So yes more, a bit more inclined to forget at night-time. (Participant 26, p.4).

Planning. This subtheme describes participants' efforts to purposefully organise certain aspects of their medication routines, such as managing their prescriptions and finding the time to go to the pharmacy/chemist. Planning seemed especially important to participants taking multiple medications. This was outlined where one participant, with a regimen of five different medications, commented:

...having to find the time to go into the chemist, remembering to refill your scripts ... I usually try to have everything ready (prescriptions refilled) when I have, you know, maybe four days left. (Participant 23, p.5).

Some participants also mentioned planning to take medication ahead of any events that might clash with their usual routine. For instance, one noted:

...when I used to go out and be a party animal. I'd generally take it before I go...(Participant 5, p.7)

Cues. In this subtheme, many participants, irrespective of the complexity of their regimen, mentioned cues that prompted them to take their medication. Such cues included visual cues (e.g., medication placement), sensory cues (e.g., taste), internal cues (e.g., noticing changes in one's own emotional or cognitive state), and contextual cues (e.g., other medications taken, or behaviours carried out simultaneously). For example, one participant spoke about incorporating a glass of water (a visual cue) into their morning routine:

...and then the glass of water is there. It's like, just take my tablets with that. So it's sort of, the water is there to remind me I haven't had them yet (Participant 14, p.4).

Similarly, another participant commented that the flavour of one of their medications served as a prompt:

... it also has a flavour, so it's kind of like a tutti-frutti flavour. Whereas before I used to go to sleep with the taste of mint in my mouth from brushing my teeth. Now I have this sweet flavour in my mouth. So, if I lie down, I'm like 'okay, time to go to sleep', I'm like 'oh, my mouth tastes normal', go to the kitchen, and get it (medication) (Participant 22, p. 6).

Additionally, those whose regimens consisted of taking more than one medication noted that taking one medication would prompt taking the other/s and perhaps even improve their adherence. This is observed where one participant commented:

...it probably helped me like not forget it as much. Because when I was just taking (medication), you know it was probably the one medication I didn't have to have at a specific time. So I was just a little bit more 'meh' about it. So I guess now I don't forget it as often. (Participant 17, p.6)

Lifestyle Factors. In this subtheme, participants described various lifestyle factors as either barriers (e.g., work, or social events) or facilitators (e.g., a consistent schedule) to adhering to their medication regimen. For example, one participant said:

...sometimes I'm like 'oh, I'll stay at yours tonight' when I'm already out, and it (medication) has to be refrigerated because it like melts. So like, it

dissolves in your mouth, but it also dissolves if there's too much humidity or if it gets too hot. So I'm like, it's a bit of a trek. (Participant 22, p.7)

It appeared that this participant perceived their social life to have an adverse impact on their ability to adhere to taking their night-time medication. Conversely, another participant stated:

I think in the morning I do have a routine, especially when uni is on or whenever I have study to do. I would wake up you know get breakfast and go take the pill (Participant 26, p.4).

This participant appeared to indicate that their consistent everyday schedule (i.e., lifestyle), may be conducive to their medication adherence.

External Supports

The theme “External Supports” encompasses the influence of different support systems in participants’ adherence to their medication regimens, regardless of the complexity. Participants described receiving support in various areas of their life, such as from health professionals, family, and friends. One participant commented on the variety of support they receive and the interaction between them:

My family are very different; they've been very supportive with my diabetes. They don't really understand the academia side of things but my friends understand the academia and not so much the diabetes side and then my partner is a bit of both. So it's kind of like I just get different support from different networks and it kind of sort of marries out. (Participant 27, p. 9)

It seems that where participants perceive support from those around them, they may feel less isolated or alone in their experiences of trying medication and creating a regimen.

Professional Support. This subtheme describes participants' experiences of receiving advice and knowledge from health professionals with regards to their medication regimen. For example, one participant stated:

...and the bulk billing doctor I saw, she was really helpful. Told me all these things I didn't even know. (Participant 19, p.5).

Participants also spoke about being comfortable seeking further information from a trusted health professional. For instance, one participant stated:

So yeah I'm pretty open to talking to my doctor about anything you know that could be wrong. Like side effects and that kind of stuff (Participant 2, p.6).

Social Support. In this subtheme, participants expressed feeling positive about having the support of significant others, such as family, romantic partners, and friends. As an example of this, one participant said:

So classic mum drills it in. She's like 'You've got to take it, you know you'll get sick and this and that will happen'. So she's definitely supportive of it... (Participant 20, p.4).

It appeared that this kind of support may aid in medication adherence for some people. Several participants also suggested that family and friends' past experiences of taking medication may have been a salient element in their expressions of support, thus exhibiting more understanding and empathy. This was noted by one participant who stated:

Mum has always encouraged it because she has been iron deficient since she was a little kid and yeah she knows the facts of it. And she's always

like “Go and get your blood tested for your iron levels” but she’s always just been conscious of it. (Participant 6, p. 4)

Some participants also expressed actively seeking support from loved ones to assist in adhering to their medication, and perhaps how this support is perceived as a positive factor in their adherence. For instance, one participant explained:

...I guess he (partner) just didn’t really know (about taking the antidepressant)... Well he knew but like he didn’t think about it or anything but until I said a couple of months ago about, ‘Can you help me remember because I’m forgetting? And it’s important that I take it’. (Participant 18, p.8)

Stigma. As a subtheme to “External Supports”, in contrast to receiving social support, some participants spoke about their experiences of stigma and stereotyping of their health concerns and medications by those around them, and thus this stigmatisation felt like a lack of support. For instance, one participant expressed:

Mum wasn’t too sure of the pill (contraceptive pill). Yeah, she obviously thought about the other connotations of me taking the pill and then got a bit upset... (Participant 26, p. 6).

Participants also expressed instances where they felt frustration or annoyance when experiencing stigma from loved ones, such that some of these instances invalidated their genuine emotional experiences, for example:

...my parents would be like annoying if any small issue arises, they’d be like ‘have you taken it?’. As if like, ‘you’re acting irrational, have you taken it?’. Which like obviously wasn’t...like I had (taken the medication) so that was kind of like annoying (Participant 18, p. 5)

However, this frustration does not appear to have influenced the participant's adherence to their medication. In addition, self-stigma also appeared evident in some interviews, such that it seemed to influence participants motivations to both start a medication and continue taking it. For example, a participant expressed:

I was like I don't need to take that...And I was like no, people who take this are really sick and that's not me. And he was like okay sure, here's a script, think about it. (Participant 7, p. 1).

Cost

There did not appear to be any differences in the experience of participants of varying regimen complexities, despite some participants having to purchase a larger number of prescribed medications. Some participants spoke positively about their medication being cheap or subsidised, and how they felt fortunate. For example, one participant said:

So this way (purchasing the generic brand medication) I can sort of like go and like it doesn't make me want to be like 'Oh, I'll have to go pay for it'...At least this way it's like easier to stick to and stuff. Like it's cheaper, it's easier all that kind of stuff yeah. (Participant 2, p. 7)

Other participants commented on having financial support from family and how this was a facilitator in the continuation of their medication regimen. One participant said:

...it costs \$60 in total. It is a bit pricey in my opinion, you know just to cough up \$60 I think it's every 30 days...I don't think it would stop me so I am lucky at the moment that mum will help me if I need it to like, she'll lend me some money to go buy it... (Participant 20, p. 5).

Some participants also noted having to purchase expensive medications at regular intervals to manage their condition. For instance, one participant who feels strongly obliged to bear the costs of their medication for the sake of their children's health cited:

Because there's so many (medications) and constantly going to the get scripts and the money of that is huge because I don't have a healthcare card...I hate it but it's kind of like, I mean the cold sores (medication) is definitely worth it, nobody else in the family has them and I do not want to pass that onto my children. (Participant 23, p. 4)

Furthermore, participants appeared to justify the high price of medications if they perceived the medication to be effective in managing their health concern. It seems as though the notion of "value for money" was an underlying factor in participants' motivations to adhere to an expensive medication. For example, one participant, who was seeking to change their medication, commented:

I was on another one and I went to the doctor and said I'm not fussed about paying the extra money, I would like to go back on (contraceptive pill type) because I prefer that it's shortened my periods... (Participant 24, p. 2).

Sense of Agency

The theme "Sense of Agency" describes an underlying sense of importance or responsibility expressed by participants to have knowledge and understanding about their prescribed medication, side effects, and impacts of non-adherence. Participants appeared to value being involved in these processes and having a sense of control. Most participants seemed to have

some degree of knowledge about their medication and its impact on them. For example, one participant noted:

I take them with a glass of water because if I don't it does make my stomach quite sore, makes me feel quite ill ... so I do have to have a lot of liquid and I always eat with them... (Participant 10, p.4)

Participants with more complex regimens, however, appeared to have a deeper level of knowledge. For instance, one participant with a complex regimen commented:

...it works for twelve hours and it's a stimulant, so obviously I take (sleep medication) because I can't sleep so I've got to be really careful when I take the (stimulant-type medication) in the mornings. I don't take it past like nine AM. (Participant 22, p.4)

Some participants expressed having undertaken their own research to gain more knowledge about their medication. One participant, who appeared to be unwilling to accept their doctor's recommendation and preferred to do their own research said:

...I get really bad headaches. And one doctor basically said that 'Oh take this medication'. He didn't really tell me what it was or what it was for. But I went home, had a Google, read up, and it was like basically epilepsy medication ... that's a bit of a big medication just to throw out there and tell me to take. Because that's going to alter a lot of things. So yeah I take doctor's advice with a high grain of salt. (Participant 6, p.7)

Choice. In this subtheme of “Sense of Agency”, it seemed as though most participants valued having a choice in the medication they were taking and the reasons for taking that medication. A sense of ownership around

medication choices may be tied to participants' adherence to their medication. For example, one participant noted how they made their own executive decisions:

I know a while back he kind of started thinking about taking me off it (medication). But then like I said, sometimes I space out a bit so I thought I'd prefer to just stick to it for like the foreseeable future anyway. (Participant 3, p.6)

Adverse Outcomes

The theme "Adverse Outcomes" relates to participants experiences of negative bodily consequences, either related to the symptoms of their health condition or as side effects of their medication regimen. These outcomes seemed to be experienced by all participants to some degree.

Symptoms of The Health Condition. In this subtheme, many participants described their experiences with the symptoms of their health condition, and how these symptoms functionally impacted areas of their life. For instance, one participant who takes medication for asthma said

...I kind of get worried that I'm going to get sick or something and if that gets onto my chest, I won't perform as well in this test or in this (sporting) competition... (Participant 20, p. 8).

Similarly, many participants spoke of their intention to adhere to their medication regimens to ensure they reduce their chances of experiencing these negative symptoms. For example, one participant stated:

...if I miss a day or two like that, the pain (period pain) doesn't come straight away which is good. But I do get like bleeding and stuff which is irritating and makes me want to be more regular with it." (Participant 2, p. 8).

Side Effects. This subtheme encompasses the participants' experience of side effects related to taking their medication or the side effects and consequences experienced if the medication dosage is missed. For instance, one participant commented on their negative experience:

...the main side effect of (medication) is dryness everything and I've already got quite a few issues with blood noses...when I get sick I can burst blood vessels quite easily in my nose and those will, I'll have quite a few blood noses...so I got sick and I just kept getting little blood noses and I thought what was it and then I realised it was (medication) that was causing it (the sore) to not heal properly. (Participant 24, p. 4)

Furthermore, participants who experienced side effects from taking their medication discussed that they continued to take the medication, despite the side effects, for example:

I would wake up in the mornings and just feel like I couldn't do anything and that I needed to sleep. But I pushed through that (Participant 16, p. 1).

Some participants also chose to no longer adhere as a direct result of their negative experience. For example, a participant expressed:

...it's (the sore) like a small cut in my nose that's not going away. That's why I'm not taking it. (Participant 24, p. 5).

Contrary to not adhering to medication to avoid side effects, some participants discussed how the negative consequences of missing the medication motivated them to adhere. Specifically, one participant expressed:

...I mean with the pill you might get your period and like spotting and you might get pregnant which is also scary...I've always been very, very, very

careful (taking the medication)...it's if you forget one or two you're not protected, end of story. (Participant 5, p. 2)

Weighing Up Pros and Cons

The theme “Weighing Up Pros and Cons” encompasses participants’ process of considering what the outcomes of taking medication would be for them. This theme seems to underlie the five previously identified themes. This process appeared to be salient for all participants, regardless of regimen complexity. For example, one participant spoke of their experience of initial negative medication side effects:

...okay I might not actually be about to die. So I'll keep going and then it (muscle spasm side effect of medication) went away after about three weeks. And then after that I was like 'yeah super worth that initial rough period. (Participant 1, p.2).

Although this participant noted some initial undesirable side effects, it appeared they perceived more value in the positive outcomes of the medication, and therefore intended to continue taking it. Some participants identified more negative factors, such as personal conflicts, when deciding whether to take medication. For instance, one participant who appeared to hold attitudes of pharmaceuticals as being harmful said:

...the whole nausea aspect of it, and I just don't know like taking something that I could not take, like putting chemicals into my body that I don't necessarily need to. Like I don't love that, but I think the benefits outweigh the negatives.” (Participant 4, p.4).

Alternatively, other participants spoke about having considered both the positive and negative aspects of continuing their medication but suggested the

benefits of the medication were a focal factor in their decision making. For example:

It tastes disgusting, that's probably the only thing I hate but that would never deter me from taking it because that's how happy I am with taking it and the results that it provides me with. (Participant 11, p.10).

Some participants also cited their explicit need for the medication to manage their condition. Thus, part of a participant's process of justifying their medication use may be a reliance on their medication for quality everyday functioning. For example, one participant said:

...without it I probably wouldn't be able to function too well. I'd be able to function but my mood would be up and down. You know quite unhappy. Easy to rile up you know, get angry, and just the way I would respond and things like that. So, for me, it was I knew I had to do it... (Participant 8, p.4)

See Table 4.1 for a brief description of the themes and subthemes.

Table 4.1*Description of Themes and Related Subthemes*

Theme	Subthemes	Description
Routines		Maintaining medication regimens in a consistent and routinised way
	Planning	Putting plans in place to ensure preparedness
	Cues	Use of prompts and reminders to ensure adherence
	Lifestyle Factors	Lifestyle barriers and facilitators of adherence
External Supports		The influence of different support systems in participants' adherence
	Professional Support	Support from trusted health professionals
	Social Support	Support from loved ones
	Stigma	Prejudice and judgement from those around them
Cost		The different role of medication cost in adhering to regimen
Sense of Agency		Having a responsibility to understand and be knowledgeable about regimen
	Choice	Making choices related to own medication and regimen
Adverse Outcomes		Experiences of negative bodily outcomes related to taking medication or lack thereof
	Symptoms of the health condition	The influence of symptoms on adherence
	Side effects	Negative side effects from taking medication or missing medication
Weighing up Pros and Cons		The process of considering the positives and negatives of the medication regimen

Discussion

The findings partially supported Temporal Self-Regulation Theory, such that the importance of some variables (intention, cues, past behaviour, planning) were identified as being important and thus may facilitate adherence. Differences in simple and more complex regimens seemed particularly salient in the role of routines, planning and sense of agency, such that those with more

complex regimens had more set routines, expressed higher importance and engagement in planning to ensure organisation and appeared to express greater knowledge related to their regimen.

Temporal Self-Regulation Theory

It appeared as though there was an underlying sense of motivation to want to adhere to medication regimens, even though participants seldom explicitly stated this intention. This is consistent with the theory, as Temporal Self-Regulation Theory suggests intention is important in executing a behaviour (Hall & Fong, 2007). Furthermore, facets of both behavioural prepotency and self-regulatory capacity were identified. These factors appeared to manifest where participants discussed the role of routines and frequent engagement in the behaviour (which is similar to past behaviour), and cues in assisting them to adhere, as shown in the “Routines” theme and related subthemes. Health professionals should consider advising patients starting new medications of the importance of a consistent routine, such that medications should be taken at the same time each day to ensure consistent and repeated execution of the behaviour such that it may become automatic over time (Wood & Rüniger, 2016).

Another facet of the theory that was commonly expressed was the role of cues. The benefits of visual cues have been previously quantitatively identified (Orr et al., 2007), however, the role of different types of cues in improving adherence has only recently been explored in relation to improving adherence (Stawarz et al., 2016). Our study further supports the notion that visual, contextual, and sensory cues may encourage adherence and aid in reducing forgetfulness, especially for those using only one medication.

Concerning self-regulatory capacity, planning was the most saliently discussed facet and appeared as a subtheme in “Routines”, however, there were also underlying notions of self-control in the “Sense of Agency” and “Routines” themes. These findings are not unusual, as previous research has shown planning (Pakpour et al., 2014), along with the perceived ease and feeling confident in enacting the behaviour (i.e., self-efficacy), can facilitate medication adherence (Lin et al., 2016).

Interestingly, and in contradiction to the theory, few participants mentioned adherence as being habitual, however, many discussed the importance of routines. This is possibly due to habit being defined as an unconscious process whereby participants have difficulty identifying their behaviour as a habit (Novoradovskaya et al., n.d.). However, often habits and routines are referred to interchangeably in the psychology domain as they both refer to regular and repeated actions (Cohn et al., 2012; Wood et al., 2002), and so this may just be a matter of semantics.

Simple vs. More Complex Regimens

The importance of having a consistent routine appeared to be more salient for participants with more complex regimens, rather than those with simpler regimens. This notion is consistent with previous literature that suggests having a daily routine is important when taking multiple medications, to promote more effective adherence (Sanders & Van Oss, 2013). Similarly, planning was more commonly mentioned by participants with more complex regimens. This is a novel finding and lends itself to being further investigated to see whether planning significantly facilitates adherence in medication regimens. To assist planning for those with complex regimens, the use of

mobile prescription management apps, such as MedAdvisor (*MedAdvisor*, n.d.), may ensure that prescriptions do not run out and are refilled in time. Health professionals and pharmacists should both consider promoting this option, which is said to increase adherence by approximately 20% (*MedAdvisor*, n.d.).

The use of cues seemed to vary across participants of different regimen complexities. Those with simple regimens appeared to rely more on the use of visual cues (e.g., medication box on bed), whilst it appeared those with more complex regimens relied on contextual cues, such that taking one medication was suggested by participants to prompt taking other medications. Future research may consider further exploring the role and effectiveness of cues by conducting experimental studies that ask participants engaged in simple medication regimens (such as the oral contraceptive pill) to choose a specific cue to pair with taking their medication. However, in the meantime and in light of these findings and previous findings by Orr and colleagues (2007), health professionals should consider promoting the use of visual or contextual cues with taking medications to their patients to assist in possibly ensuring greater adherence.

In addition, although not a facet of Temporal Self-Regulation Theory, there appeared to be differences in knowledge and knowledge-seeking behaviour between those with simple and more complex regimens. Those with more complex regimens appeared to express a greater degree of knowledge and knowledge-seeking related to their condition and specific medications. This could be due to more complex regimens being related to multi-morbidity or more complex health conditions where knowledge is imperative to treatment,

whereas more simple regimens may be related to less severe or fewer conditions. This is an important consideration and should be investigated in future research. However, disease and medication specific knowledge is said to be strongly and positively associated with health literacy (Walker et al., 2007), which may suggest that our sample is not highly knowledgeable in their specific disease or medication, but rather are more health literate in general. However, the relationship between health literacy and medication adherence has not been explored extensively (Wolf et al., 2007), even in simple regimens, and may provide avenues for future research in this area.

Non-Temporal Self-Regulation Theory Variables

The findings also identified several variables influencing adherence that are not included in Temporal Self-Regulation Theory. The cost of medications was not a barrier to adherence, which is inconsistent with the large majority of previous research in this area (Huang et al., 2020). This may be due to the Australian Pharmaceutical Benefits Scheme (PBS) (*The Pharmaceutical Benefits Scheme*, n.d.) which subsidises the cost of medications for most health conditions, making them more affordable and therefore accessible. Thus, research related to the cost of medications in the US and other countries may not be applicable in an Australian context.

Furthermore, the avoidance of negative symptoms of the health condition seemed to be associated with adherence. This disease-specific factor is slightly different to what has been identified in previous research, which tends to suggest that individuals view medication adherence as being necessary to be able to cope with their condition (Beusterien et al., 2008; Kelly et al., 2014). The role of avoidance of negative symptoms in facilitating medication

adherence is common for those taking prophylactic medication (e.g., to prevent asthma symptoms) (Craig & Wright, 2012), however, it should be further studied in those taking medications to treat a condition, such as antidepressants. Perhaps incorporating questions explicitly asking individuals if they take their medication to avoid possible negative symptoms of their condition, is one way to explore this further. The importance of having support networks, both professional and social, was also identified, which is not unusual (Edwards, 2006). However, increased support has shown to be conducive to better adherence (Kelly et al., 2014) which was not explicitly stated in our study. Many participants suggested they did not care too much about the lack of support or stigma they received and continued with their regimen regardless.

The use of an inductive and deductive approach has allowed for the identification of these important variables that are not part of Temporal Self-Regulation Theory. This provides opportunities for future research to test Temporal Self-Regulation Theory quantitatively, but with the addition of these variables to explore whether they can predict additional variance in medication adherence beyond that of the theory. Such extensions to theories are common in the literature (Liddelow, Mullan, & Novoradovskaya, 2020).

Limitations

While the current study was successful in identifying different psychological variables as being important in different regimen complexities, the study is not without its limitations. The most salient limitation is that we were unable to capture a sample with “complex” regimens, with only five participants having between three and five medications. It appears that our

study captured a sample of “simple” (one or two medications) and “not so simple” medication regimens. Related to this, our sample was a university sample and these samples tend to be younger and more highly educated compared to the general public (Hanel & Vione, 2016). This may explain why there was a low number of participants who expressed non-adherence because they “know better” and perhaps have greater health literacy. It may also explain why knowledge and knowledge-seeking was a salient theme throughout the findings. However, although we captured fewer complex regimens than we would have liked, we still had a degree of complexity with participants taking numerous medications. This study has been able to shed light on an under researched, yet important, area of adherence. The findings show there are differences in what is viewed as being important in adhering to simple and more complex regimens, despite the limited complexity of our sample. Future research should consider these important preliminary findings and apply Temporal Self-Regulation Theory quantitatively and qualitatively to samples engaged in operationally defined simple regimens and complex regimens to explore whether these differences are also apparent.

Conclusions

The present study sought to explore the utility of Temporal Self-Regulation Theory in helping to explain medication adherence in people’s daily lives, specifically in how they adhere to their medication regimens, and whether there are any differences in how the theory operated in adherence to different medication regimen complexities. Six themes that influence adherence were identified. Differences between regimen complexities

appeared, such that participants who take between three and five medications spoke more on the importance of having a consistent routine, planning, and seeking knowledge. Participants taking only one medication highlighted the importance of implementing cues, specifically visual, to assist in adherence. The findings show some support for Temporal Self-Regulation Theory, specifically intention, past behaviour, cues, and planning, but many non-psychological influences were also identified, such as the cheap cost of medications, support from health professionals and friends, the experience of side effects, avoiding negative symptoms of the condition and being involved in the process. However, complex regimens were not necessarily captured in the university sample and therefore future research should consider applying the theory to samples with distinct simple and complex regimens. Future research may also consider investigating the role of visual or contextual cues in simple regimens to see if adherence can be improved over time.

Chapter 5: Adherence to the Oral Contraceptive Pill: The Roles of Health Literacy and Knowledge

Introduction to Chapter 5

In the previous chapters (Chapters 2, 3 and 4) I established partial support for Temporal Self-Regulation Theory in predicting medication adherence. Now that I knew the theory and some of its constructs were determinants of adherence I wanted to target these determinants in an intervention to improve adherence. However, to do this I first needed to select a specific type of medication to be targeted as the previous chapter identified differences in the importance of Temporal Self-Regulation Theory variables in different regimen complexities. As approximately 80% of women report using the oral contraceptive pill at least once in their life (Daniels & Abma, 2018) I decided this population was suitable as it was a simple regimen (taking one pill daily), and the population would not be too difficult to recruit. Similarly, it is important that adherence to the pill is perfect (e.g., taken at the same time every day) to ensure the full benefits of it (Trussell, 2011).

Now that I had my population of interest, before I could create and implement an intervention to improve adherence to the oral contraceptive pill, I needed to ensure that there was sufficient variability in levels of adherence to the pill. I also used this opportunity to further explore and understand the differences in adherence measures by using two measures to measure adherence to the pill, the Medication Adherence Report Scale (Horne & Weinman, 1999) and the Timeline Follow-Back (Liddelow, Mullan, & Novoradovskaya, 2020; Sobell & Sobell, 1992). The Medication Adherence

Report Scale (Horne & Weinman, 1999) contains 5 items relating to adherence behaviour and has yet to be used in this thesis. It should not be confused with the Medication Adherence Rating Scale (Thompson et al., 2000) that was used in Chapter 3. Both the Medication Adherence Report Scale (Horne & Weinman, 1999) and the Timeline Follow-Back (Liddelow, Mullan, & Novoradovskaya, 2020; Sobell & Sobell, 1992) can be considered measures of behaviour (rather than measures of attitudes/beliefs), but the possible differences in findings between the two has not been previously investigated. I conducted an online survey, assessing adherence to the pill, and because of the findings in the previous chapter (Chapter 4), that knowledge seemed to be important in adherence, I included measures of knowledge (specifically to the pill) and health literacy (generally) to further explore their role in adherence specifically to the oral contraceptive pill. Health literacy has previously been identified as being important in medication adherence (Martin et al., 2005), however had not been previously investigated specifically in relation to adherence to the oral contraceptive pill.

Although this chapter does not focus on Temporal Self-Regulation Theory or any of its variables, this chapter is an important linking chapter between the exploration of the theory in medication adherence, and developing, and piloting an intervention to improve adherence in a specific population. This chapter is imperative in ensuring there is enough variance in adherence to warrant an intervention targeted at improving adherence to this preventative medication (see Chapter 6). Similarly, because up until now Temporal Self-Regulation Theory has only been partially supported in the previous chapters, I decided to use this opportunity to quantitatively assess

some of the factors that were identified as being important in the qualitative exploration of adherence (Chapter 4) to see if these factors are worthwhile additions/expansions to the theory.

Published:

Liddelow, C., Mullan, B., & Boyes, M. (2020). The roles of health literacy and knowledge in adherence to the oral contraceptive pill. *Health Psychology and Behavioural Medicine*, 8(1), 587- 600.

<https://doi.org/10.1080/21642850.2020.1850288>

Author	Contribution	I acknowledge that these represent my contribution to the above research output Signed:
Caitlin Liddelow	Development of research question, data collection, data management, data analysis, interpretation of results, and manuscript preparation, reviewing and editing of drafts	
Barbara Mullan	Assisted with development of research question, and manuscript preparation, reviewing and editing of drafts	
Mark Boyes	Assisted with development of research question, and manuscript preparation, reviewing and editing of drafts	

Abstract

The oral contraceptive pill is the most widely used method of contraception and when adhered to perfectly is 99% effective at preventing pregnancy. However, adherence to the pill is relatively low. Knowledge has shown to be important in continuation of the pill, and previous research shows the importance of health literacy in adhering to medication in chronic illnesses, but its role has yet to be explored in this behaviour. This cross-sectional study examined the associations between health literacy, knowledge of the pill and adherence, as well as the predictive ability of these two variables and their interaction, in predicting adherence. Recruited through CloudResearch, 193 women ($M_{\text{age}} = 32.63$ years, $SD = 5.98$) residing in the United States completed the Health Literacy Skills Instrument – Short Form, a previously validated measure of oral contraceptive pill knowledge and the Medication Adherence Report Scale. Results showed a strong positive correlation between health literacy and adherence ($r = .76$) and moderate associations between health literacy and knowledge ($r = .42$), and knowledge and adherence ($r = .42$). The final model of the hierarchical multiple regression accounted for 59.8% of variance in adherence, with health literacy ($\beta = .69$) and length of time taking the pill ($\beta = .13$) the only significant predictors of adherence. Family planning clinics should consider assessing the patient's health literacy skills before prescribing the pill to ensure patients fully understand the requirements.

Introduction

The oral contraceptive pill, otherwise known as the ‘pill’, is the most commonly used method of contraception in economically developed countries (United Nations, 2015). Between 2015–2017, approximately 80% of sexually active women in the US, between the ages of 15 and 49, indicated they had ever used the oral contraceptive pill (Daniels & Abma, 2018). The pill is highly effective at preventing pregnancy when adhered to perfectly, such that only 0.3% of women report falling pregnant in the first year (Trussell, 2011). In addition, whilst most commonly being used as a method of contraception, the pill also has many non-contraceptive related uses including reducing menstrual bleeding, menstrual cramps and menstrual-related migraines, and reducing the risk of ovarian cysts and the occurrence of acne (Arowojolu et al., 2012; Dayal & Barnhart, 2001; Edelman et al., 2007; Vercellini et al., 2003).

Despite the numerous benefits, affordability and ease of use, adherence to the pill is still relatively low (Molloy et al., 2012; Rosenberg et al., 1998). Studies have shown that perfect adherence is rare with approximately 50% of women reporting missing their pill at least once per month (Molloy et al., 2012; Rosenberg et al., 1998). It is also estimated that approximately 22% of women taking the pill miss two or more per month (Rosenberg et al., 1998). This less than perfect adherence reduces the effectiveness of the pill to only 91%, reduced from 99.7% (Trussell, 2011), and it is suggested to be the primary reason for unintended pregnancies in women using the pill (Cleland et al., 2012, 2014).

Much of the research exploring adherence to the pill has focused on the correlates of non-adherence or misuse rather than understanding the factors

associated with better adherence (Tomaszewski et al., 2017). One factor associated with higher levels of adherence to the pill is knowledge of the pill, both perceived (Tomaszewski et al., 2017) and actual (Hall et al., 2014). Both studies showed that women who report believing they have higher knowledge of the pill or actually exhibit greater knowledge, reported higher levels of adherence and intent to continue taking the pill (Hall et al., 2014; Tomaszewski et al., 2017). Women with a higher knowledge of how the pill works, its benefits, side effects and use were up to 6 times more likely to continue taking their pill compared to less knowledgeable women (Hall et al., 2014). Levels of knowledge were lower in younger women, perhaps suggesting that as age increases, so does knowledge of the pill.

Although not specific to the oral contraceptive pill, due to the lack of research, another factor that has shown to be associated with increased adherence to medication is health literacy. It is estimated that approximately 60% of adults have poor or inadequate health literacy skills (Australian Commission on Safety and Quality in Health Care, 2014). Research indicates that increasing levels of health literacy may be an effective way to improve adherence to treatment and medications (Baker, 2006; Wolf et al., 2007; Zhang et al., 2014). Health literacy refers to the knowledge, motivation, competency, understanding and appraisal of general health-related and healthcare information, by applying knowledge to the reading and understanding of medicine and nutrition labels, and understanding instructions provided by doctors (Sørensen et al., 2012). One meta-analysis identified consistent positive associations between higher health literacy levels and a greater ability to appropriately take and adhere to medications (Berkman et al., 2011). A

second meta-analysis found that patients with higher levels of health literacy were 14% better at adhering to their medications, compared to those with low health literacy, and that health literacy interventions effectively improved adherence to treatment and medications (Miller, 2016). Albeit both associations were considered weak ($r = .14$ and $.16$ respectively). Similarly, another meta-analysis identified that 14 out of 20 identified studies exploring the relationship between health literacy and medication adherence in chronic disease populations found positive associations between the two, with zero studies reporting a negative association (Neter & Brainin, 2019). However, two of the discussed meta-analyses (Berkman et al., 2011; Neter & Brainin, 2019) report a low strength of evidence, mostly due to the research designs, and thus these associations may be biased.

Previous research has shown there is a relationship between health literacy and knowledge in chronic illness (Chajae et al., 2018; Yeh et al., 2018), suggesting that those with higher health literacy tend to also have higher levels of knowledge regarding the chronic illness they (Chajae et al., 2018; Yeh et al., 2018). In a narrative review synthesising the relationship between health literacy, knowledge and adherence to anticoagulants in cardiovascular disease there was an overall positive relationship between health literacy and knowledge (Cabellos-García et al., 2018). Participants with lower levels of health literacy and knowledge were also found to be less likely to adhere to their medications (Cabellos-García et al., 2018), and other studies have reported similar findings between health literacy, knowledge and adherence (Rolls et al., 2017). While there is some research examining knowledge and adherence to the pill (Hall et al., 2014), there is currently no literature which

explores the influence and relationships between health literacy, knowledge and adherence to the oral contraceptive pill. Therefore, this study aimed to do so. Health literacy is often explored in specific illnesses (e.g., cardiovascular disease) or specific populations (e.g., Latinx) (Office of Disease Prevention and Health Promotion, 2020), but given that approximately 80% of women in the US report ever using the pill (Daniels & Abma, 2018), and the negative consequences of less than perfect adherence, it is important to understand the potential role that health literacy plays in this behaviour to ensure women with inadequate health literacy are provided with the necessary skills to effectively adhere to the pill.

In addition, this study also sought to explore the interaction between health literacy and oral contraceptive pill knowledge in adherence to the pill. As general health knowledge and the application of this knowledge are key aspects of health literacy (Sørensen et al., 2012), the interaction between specific oral contraceptive pill knowledge and health literacy was considered to be an interesting avenue to explore. It may be that medication or disease-specific knowledge interacts with health literacy (and general health knowledge) to improve adherence. Knowledge in this study specifically refers to knowledge of the oral contraceptive pill and its risks, benefits, side effects, effectiveness, use and mechanisms of action (Hall et al., 2014; Hall et al., 2010). It was hypothesised that based on previous literature, there would be a positive and significant association between (i) health literacy and adherence, (ii) knowledge of the oral contraceptive pill and adherence, and (iii) health literacy and knowledge. Secondly, it was hypothesised that after controlling for age and education, both health literacy and knowledge would be directly

associated with adherence to the oral contraceptive pill. Thirdly, it was hypothesised that knowledge would moderate the relationship between health literacy and adherence, such that there would be a significant positive association between health literacy and adherence but at high levels of knowledge.

Methods

Procedure

A cross-sectional design was used, and the study was approved by the University's Human Research Ethics Committee (HRE2017–0173). Data were collected online through the crowdsourcing platform CloudResearch (cloudresearch.com), owned by Amazon Mechanical Turk, in early 2020. To be eligible for participation, participants were required to have female reproductive anatomy and be currently taking the oral contraceptive pill (either the combination pill or the progestogen-only pill). All eligible participants provided informed and once consent was provided, all participants completed measures of general health literacy, knowledge of the oral contraceptive pill, adherence to the oral contraceptive pill over the previous month and demographic questions both related to the oral contraceptive pill and general demographics. The online questionnaire was completed on Qualtrics using a device of the participants choice. The survey took no longer than 15 mins to complete and participants were reimbursed \$2USD for their time.

Measures

Health Literacy

General health literacy was measured using the Health Literacy Skills Instrument – Short Form (HLSI-SF; Bann et al., 2012). This measure is a shortened 10-item version of the original 25-item Health Literacy Skills Instrument (McCormack et al., 2010). The short form contains five items that measure print literacy (reading, locating, and understanding health information), two that measure numeracy (seeking and using quantitative information), two measuring oral literacy (listening effectively and understanding), and one item that requires the participants to locate health information through the internet. Items required participants to listen to short audio clips, watch videos or examine print documents such as pamphlets and hospital maps. For each item, there is only one correct answer, with correct answers summed together to create a final score out of 10. Final scores of 6 or below are considered ‘inadequate health literacy’ and scores equal to or greater than 7 are considered ‘adequate health literacy’ (Bann et al., 2012). The instrument showed acceptable reliability in our sample ($\alpha = .75$).

Knowledge

Levels of oral contraceptive pill knowledge were measured using an established measure created by Hall et al. (2013). The 41-item measure assesses the six main dimensions of oral contraceptive knowledge: mechanism of action (‘The pill has either a combination of estrogen and progestin or progestin-only’), effectiveness (‘The regular use of certain medications can reduce how well the pill works’), use (‘The pill is a daily hormonal contraceptive’), side effects (‘The pill causes weight gain’), risks (‘You cannot get sexually transmitted infection while taking the pill’) and benefits (‘Does the pill make menstrual cramps better, worse or have no effect?’). The questions

employed a range of formats such as true/false (10 items), multiple choice (15 items) and alternative choice (16 items). Each item only had one correct answer. All correct answers were summed to create a final score out of 41. The higher the score, the better knowledge the participant has of the oral contraceptive pill.

Adherence to The Pill

Adherence to the oral contraceptive pill over the previous month was measured using the Medication Adherence Report Scale (MARS; Horne & Weinman, 1999), adapted to ask questions related to oral contraceptive pill adherence (Molloy et al., 2012). The measure contains five items asking participants about their adherence, or lack thereof, to the oral contraceptive pill. Each item was answered on a 5-point Likert scale from 1 = never to 5 = always (e.g., 'I forgot to take my oral contraceptive pill'). All items were reverse coded for ease of interpretation, and scores were summed, with higher scores meaning greater adherence over the previous month. The MARS demonstrated reliability in our sample ($\alpha = .97$).¹

Demographics

Participants were asked several demographic questions related to sexual activity, pregnancy, details of their oral contraceptive pill (name, length of time used, the reason for taking, current routine), experience obtaining the oral contraceptive pill, and any instructions they were provided when prescribed.

¹ As previous chapters had identified differences in self-report measures of medication adherence, the Timeline Follow Back was included in the online survey. However, there were large amounts of data missing from this measure as well as inconsistencies in the way it was completed by participants. This made the data difficult to interpret and therefore the decision was made to remove the measure from the chapter. However descriptive analysis of those that did complete it shows an adherence range of 2-14 out of a maximum of 14, indicating variability in adherence to the pill.

General demographics such as age, gender, annual income, education, and ethnicity were also asked.

Data Analysis

All data were analysed using IBM SPSS Statistics Version 26 (IBM Corp, 2019). Cases that selected they did not take the pill ($n = 80$) or did not provide informed consent ($n = 3$) were removed before a missing values analysis being conducted. A missing values analysis was conducted on the remaining cases and Little's MCAR test showed that data were not missing completely at random, $\chi^2(2525) = 2789.62, p < .001$. A total of 49 participants missed one or more items in the knowledge measure, with 24 of these missing 5% or more. A large majority of the missing data points were in a single subscale of the knowledge measure, with each item missing between 5.2–6.7% of its data. As listwise deletion of cases would be inappropriate, multiple imputation with 5 imputations using fully conditional specification was conducted. Subsequent analysis was conducted on pooled statistics.

Descriptive statistics and Pearson's correlation coefficients were conducted on the unstandardised variables. Variables were standardised before conducting the hierarchical multiple regression analysis to reduce multicollinearity (Aiken & West, 1991). A Mann–Whitney U test was conducted to examine any differences in adherence and health literacy in those who missed any items on the knowledge measure and those that did not. Results showed significant differences in adherence to the pill between those missing at least one item and those not missing any, $U = 2234.00, z = -3.91, p < .001$, such that those not missing any items reported greater adherence. Similarly, the results indicated significant differences in health literacy

between those that missed an item and those that did not, $U = 2129.50$, $z = -4.18$, $p < .001$. Those who missed no items exhibited better health literacy.

Education level was not significantly correlated with any of the key variables, so the decision was made to remove it from the regression analysis. However, age, ethnicity and years taking the pill were all significantly correlated with either health literacy, knowledge or adherence and were subsequently controlled for in the regression. At step one age, ethnicity and years taking the pill were entered and controlled for. At step two health literacy was entered, at step three oral contraceptive pill knowledge was entered, and at step four, the interaction between health literacy and knowledge was entered.

Results

Participants

After the removal of cases, a total of 193 participants remained in the sample ($M_{\text{age}} = 32.63$ years, $SD = 5.98$). All participants identified as female, 60.6% identified as Caucasian and 26.4% identified as African American, 79% of participants had at least a bachelor's degree and 86% earned USD 75,000 or less annually. Concerning the oral contraceptive pill, 86% of participants reported taking the combination pill. Time taking the pill ranged from 1 month up to 37 years, with a mean of 3.99 years. A majority of the sample was taking the pill for contraception (53.6%), however, other reasons such as to regulate periods (18.2%), to help with acne or skin problems (10.9%) or to reduce the effects of menstrual cramps or endometriosis (9.8%) were also common. With regards to sexual activity and pregnancy demographics, 85.5% of the sample reported being sexually active, 45.6% reported ever being pregnant and

48.19% had children. Participants' health literacy was largely inadequate, with $N=116$ exhibiting inadequate health literacy (≤ 6 out of 10 correct responses) and $N = 77$ exhibiting adequate health literacy (>7 out of 10 correct responses). In total, participants' knowledge of the pill was on the midpoint of the scale ($M = 20.38$ out of 41, $SD = 5.64$) and adherence in the sample was good ($M = 18.70$ out of 25, $SD = 6.85$).

Bivariate Analyses

A Chi-square test of contingencies indicated a significant difference in health literacy levels and ethnicity, $\chi^2(3, N = 191) = 20.07, p < .001$, such that those who identified as African American were more likely to have inadequate health literacy ($n = 42$) compared to adequate health literacy ($n = 7$). Results were similar for those that defined as Latinx, with $n = 8$ having inadequate health literacy, while $n = 4$ had adequate health literacy. In comparison, there was a relatively even number of people who identified as Caucasian having inadequate ($n = 57$) or adequate ($n = 60$) health literacy in this sample.

An independent samples t -test was computed to examine any differences in the (i) mean knowledge scores between the two health literacy groups, and (ii) adherence levels in those with inadequate and adequate health literacy. There was a significant difference between the two health literacy groups and mean knowledge score. Those with adequate health literacy ($M = 23.26, SD = 5.38$) achieved a mean of 4.78 more correct knowledge questions, 95% CI [3.30, 6.28] compared to those with inadequate health literacy ($M = 18.47, SD = 4.97$), $t(189)=6.30, p < .001$, Hedges' $g = .83$. Similarly, there was a significant difference in adherence between the two health literacy groups, with those with adequate health literacy ($M = 24.23, SD = 2.13$) reporting better

mean adherence to the oral contraceptive pill by 9.19 points, 95% CI [7.91, 10.47] than those with inadequate health literacy ($M = 15.03$, $SD = 6.43$), $t(146.63) = 14.07$, $p < .001$, Hedges' $g = 1.86$.

Table 5.1 shows the means, standard deviations, and correlations between the main demographic variables, health literacy, knowledge, and adherence. Age was significantly weakly positively associated with number of years taking the pill ($r = .29$, $p < .001$) and knowledge ($r = .15$, $p = .040$). Education level was not significantly associated with the level of health literacy, knowledge, or adherence. Health literacy was significantly associated with number of years taking the pill ($r = .27$, $p < .001$), knowledge ($r = .42$, $p < .001$) and adherence ($r = .76$, $p < .001$). Knowledge was moderately correlated with number of years taking the pill ($r = .24$, $p = .001$) and adherence ($r = .40$, $p < .001$).

Table 5.1

Means, Standard Deviations and Correlations between Key Variables

	M	SD	1	2	3	4	5	6
1.Age	32.63	5.99	-	-.01	.29**	.10	.15*	.07
2.Education	-	-		-	.01	-.02	-.02	-.03
3.Number years taking pill	3.99	5.58			-	.27**	.24**	.33**
4.Health Literacy	5.26	2.42				-	.42**	.76**
5. Knowledge	20.38	5.64					-	.40**
6. Adherence	18.70	6.85						-

Note. M = mean, SD = standard deviation * $p < .05$, ** $p < .01$

Hierarchical Multiple Regression Analysis – Predicting Adherence

In step one of the analysis, age, ethnicity, and number of years taking the pill were entered and accounted for a significant 17.4% of the variance in adherence to the oral contraceptive pill, $R^2 = .17$, $F(3, 179) = 12.53$, $p < .001$. In step two health literacy was entered and accounted for a significant 41.8% of the variance in adherence to the oral contraceptive pill, $\Delta R^2 = .42$, $\Delta F(1, 178) = 182.00$, $p < .001$. In step three knowledge was added to the regression and accounted for no additional variance, $\Delta R^2 = .006$, $\Delta F(1, 177) = 2.68$, $p = .103$. In step four the interaction term between health literacy and knowledge was added to the model and accounted for no additional variance, $\Delta R^2 = .001$, $\Delta F(1, 176) = 0.41$, $p = .521$. In combination, the three variables accounted for a total 59.8% of the variance in adherence to the pill, $R^2 = .60$, $F(6, 176) = 834.61$, $p < .001$. The only significant predictors in the final model were the number of years taking the pill ($p = .018$) and health literacy ($p < .001$). See Table 5.2 for the regression coefficients.

Table 5.2

Unstandardised (B), Standardised Regression Coefficients (β), and Squared Semi-Partial Correlations (sr^2) for Each Predictor and Step in the Hierarchical Multiple Regression

Variable	B [95% CI]	β	sr^2	p	R^2	ΔR^2	F	ΔF (df1, df2)
Step 1				.000	.174	.174	12.52	12.52 (3,179)
Age	-.04 [-.20, .11]	-.04	.00	.583				
Ethnicity	1.09 [.53, 1.65]**	.27	.07	.000				
Numbers of years taking pill	.33 [.16, .51]**	.28	.07	.000				
Step 2				.000	.591	.418	64.40	182.00 (1, 178)
Age	-.05 [-.16, .06]	-.04	.00	.389				
Ethnicity	.12 [-.30, .55]	.03	.00	.562				
Number of years taking pill	.17 [.04, .29]*	.14	.02	.009				
Health literacy	4.90 [4.18, 5.51]**	.71	.42	.000				
Step 3				.000	.597	.006	52.55	2.68 (1, 177)
Age	-.06 [-.17, .05]	-.05	.00	.314				
Ethnicity	.09 [-.33, .51]	.02	.00	.665				
Number of years taking pill	.15 [.03, .28]*	.13	.01	.015				
Health literacy	4.70 [3.95, 5.44]**	.69	.35	.000				
Knowledge	.60 [-.12, 1.30]	.09	.00	.103				
Step 4				.000	.598	.001	43.71	0.41 (1, 176)
Age	-.06 [-.17, .05]	-.05	.00	.317				
Ethnicity	.08 [-.34, .50]	.20	.00	.698				
Number of years taking pill	.15 [.03, .28]*	.13	.01	.018				
Health literacy	4.73 [3.97, 5.50]**	.69	.34	.000				
Knowledge	.51 [-.23, 1.27]	.08	.00	.174				
Health literacy X knowledge	.26 [-.55, 1.10]	.03	.00	.521				

Note. CI = confidence intervals, significant variables are emphasised in bold

* $p < .05$, ** $p < .01$

Discussion

In this study, we explored the associations between health literacy, knowledge, and adherence to the oral contraceptive pill. The primary findings of this study suggest that health literacy has the strongest association with adherence to the oral contraceptive pill and explains the most variance in adherence. However, the length of time taking the pill is also important. The findings also suggest that adherence to the oral contraceptive pill is relatively high, however improving health literacy skills may be a way to improve adherence to the pill and subsequently improve its effectiveness at preventing pregnancy and improving its non-contraceptive benefits.

We found significant positive associations between health literacy and adherence, knowledge and adherence, and knowledge and health literacy. All three correlations were positive, however, the association between health literacy and adherence to the pill was the strongest and the remaining two associations were moderate. This association is consistent with previous research which also found a significant association between health literacy and medication adherence across a range of chronic diseases (Mayo-Gamble & Mouton, 2018; Miller, 2016; Osborn et al., 2011; Zhang et al., 2014). We have now also demonstrated that this is true for taking the pill.

We found a significant positive association between oral contraceptive knowledge and adherence, which supports previous research (Hall et al., 2014; Tomaszewski et al., 2017), however, this became non-significant when health literacy was included, perhaps due to shared variance. This suggests knowledge, along with health literacy, is related to adherence such that those with higher knowledge of the pill tend to also have better adherence to the pill.

Women who attend pill related check-ups or to receive repeat prescriptions could be asked a few questions related to the oral contraceptive pill, such as its use, benefits, or mechanisms of action, to get an understanding of their knowledge related to the pill. If their knowledge is low, educational resources or leaflets should be provided to educate the individual as well as to hopefully improve their overall health knowledge, which is an aspect of health literacy (Sørensen et al., 2012). Similarly, when women are first prescribed the pill they should receive a simple educational leaflet from the health professional (Little et al., 1998) to ensure they are knowledgeable before they begin taking the pill, rather than just the leaflet in the pillbox which tends to have poor readability and is read by a minority of people (Koo et al., 2003; Raynor & Knapp, 2000).

However, providing educational leaflets and asking health-related questions may be ineffective in improving knowledge if the patient has inadequate health literacy. This is further supported by our finding of a significant positive association between health literacy and oral contraceptive pill knowledge. This relationship has previously also been identified in chronic illness understanding (Chajae et al., 2018; Gazmararian et al., 2003; Van Der Heide et al., 2014; Yeh et al., 2018), such that patients with low health literacy also have less of an understanding of their chronic illness. Although associations are unable to show causality, knowledge is a component of health literacy (Sørensen et al., 2012) and therefore our findings may demonstrate that perhaps general health literacy skills need to be targeted and improved first, before patients are provided with specific oral contraceptive pill knowledge.

Health literacy was the most significant predictor of adherence to the oral contraceptive pill with neither knowledge nor the interaction between health literacy and knowledge significant predictors. This finding is not uncommon in the literature for other chronic diseases (Lee et al., 2017; Murray et al., 2004). It may be that knowledge of the oral contraceptive pill is important for understanding how to adhere to the pill correctly but is not enough to predict adherence. It may be that additional determinants of adherence to the pill, such as perceived behavioural control/self-efficacy (Ajzen, 2011; Molloy et al., 2012) or beliefs related to medication (Horne & Weinman, 1999) need to be explored further. For instance, women who view taking the pill as 'easy' and 'simple' may have greater adherence and similarly, those that view taking the pill more positively may also exhibit greater adherence. Perceived behavioural control and self-efficacy have previously been identified as being significant predictors in adherence to the pill, although only in one study (Molloy et al., 2012). Similarly, in an older study, negative beliefs about the oral contraceptive pill negatively influenced both intentions to use and adherence to the pill (Moore et al., 1996). Both psychosocial variables should be further investigated to see if they are influential above and beyond health literacy.

Similarly, due to the moderate association between health literacy and knowledge, it is possible that the basic knowledge of the oral contraceptive pill (e.g., understanding how to read the medication label and instructions) was accounted for in the health literacy measure. However, further research is needed to explore the relationship between health literacy and knowledge of the pill. These findings suggest that family planning clinics should consider

assessing the patient's level of health literacy, perhaps using an assessment tool designed for use in clinical settings, such as the Newest Vital Sign (NVS; Osborn et al., 2007; Weiss et al., 2005). By doing so, they can grasp a deeper understanding of the patients understanding of health-related information and provide additional resources, or spend more time educating the patient on understanding the labels and instructions associated with their oral contraceptive pill.

Health professionals need to spend more time and effort with patients with poorer health literacy to ensure they fully comprehend what is required of them, with clinicians providing strategies such as patient-centred communication (e.g., 'what do you already know about the pill?'), being clear about health topics (e.g., using plain language and attempting to match the patient's vocabulary) and confirming understanding with the patient before allowing them to leave (Kountz, 2009; Sudore & Schillinger, 2009). If this is not viable due to time restraints, it may be worthwhile referring patients to lay health educators in their community. Lay health educators can provide effective communication and health support across all literacy levels (Auger & Verbiest, 2007) if the clinician does not have the appropriate skills to do so. Also, health professionals need to ensure they are creating an empowering environment such as making forms clear and easy to read, as well as ensuring they are up to date with their medical and health education accreditations so they are best able to assist their patients (Sudore & Schillinger, 2009). Similarly, in interventions aimed at improving health literacy it may be that targeting the individual components of health literacy (e.g., reading) will be more useful in yielding significant improvements in health literacy, rather than

trying to target the entire concept at the one time. Small changes in general literacy can result in a better overall application of the skills to specific health situations (Nutbeam et al., 2018).

It is also important to acknowledge that length of time taking the pill was also predictive of adherence. Interpreted in conjunction with the significant positive association between the number of years taking the pill and adherence, it suggests that females who have been taking the pill for longer are better at adhering. This relationship should be explored further to see whether the behaviour has perhaps become routinised or even become automatic such that it is now a habit. Habit has previously shown to be associated with better adherence to the oral contraceptive pill (Murphy et al., 2018), but only in a single study. The role of habit in understanding adherence to the oral contraceptive pill could be further explored within theories of behaviour that incorporate habit, such as Temporal Self-Regulation Theory (Hall & Fong, 2007) as other psychological variables may be more predictive of adherence than habit. Temporal Self-Regulation Theory has previously been shown to be useful in predicting general medication adherence (Liddelow, Mullan, & Boyes, 2020b).

Finally, approximately 60% of our sample exhibited inadequate health literacy, which is consistent with government statistics (Australian Commission on Safety and Quality in Health Care, 2014). Our findings also showed there to be significant disparities in the level of health literacy (inadequate and adequate) based on ethnicity. Of the participants that identified as African American, 86% exhibited inadequate health literacy. Further, those with inadequate health literacy were less knowledgeable about the oral

contraceptive pill and reported worse adherence to the pill. These findings provide insight into the groups where improvements in health literacy are needed, and also reflects the possible systemic inequalities in modern society with regards to education and opportunities to obtain access to health-related information. This finding may also be related to the health literacy measure itself, such that it is not culturally tailored to specific minority populations and rather created for majority populations. However, there are currently no health literacy measures tailored to African American populations (Estrella & Allen-Meares, 2020).

Strengths and Limitations

To the best of our knowledge, this is the first study to examine the relationships between health literacy, knowledge, and adherence to the oral contraceptive pill. A strength of the study is the wide demographic surveyed. This increases the generalizability of the findings and associated implications for various populations outside of the current sample. However, it is important to acknowledge that most users of the pill tend to be younger than the sample in this study and therefore the findings should be interpreted with this in mind. Furthermore, there are limitations to this study, including the use of a cross-sectional design, which precludes any conclusions regarding the direction of the associations as well as causality. In addition, crowdsourcing platforms also present a range of their own limitations such as the presence of bots and the use of duplicate IP addresses (Cheung et al., 2017). However, to reduce the occurrence of these limitations, specific settings and options were selected on CloudResearch to ensure the validity and quality of our data. Furthermore, the alternative choice items in the knowledge measure (Hall et al., 2014) seemed to

present issues with missing data. Each of the 16 items presented in this format was missing a considerable amount of data compared to the true/false and multiple-choice formatted questions. Similarly, those with lower health literacy levels were more likely to miss items on this measure indicating the items or the way it was presented was too complex for a sample largely comprised of individuals with inadequate health literacy. Future research may consider removing these alternative choice questions to ensure the simplicity of the measure for participants. The final limitation of the current study is the measurement of adherence to the pill. Direct measures of adherence to the pill, such as through serum or urine samples (Hall et al., 2010), would provide better estimations of adherence, however, are more expensive and difficult to administer, particularly in an online survey and therefore self-report was the preferred chosen measure of adherence despite limitations associated with self-report measures. Our measure of adherence was skewed towards greater adherence, however still presented a range of adherence, from the lowest possible score to the highest.

Conclusion

The present study explored the associations between health literacy, knowledge of the oral contraceptive pill and adherence, as well as the predictive ability of these two variables in predicting adherence to the oral contraceptive pill. Results showed that health literacy and knowledge are both significantly positively associated with adherence; however, health literacy was the strongest predictor of adherence to the pill in multi-variate analyses. As this is the first study to explore these relationships, future research is needed to replicate the findings of this study. However, the findings suggest that health

professionals should consider assessing patient's health literacy skills when pre- scribing the oral contraceptive pill to ensure patients fully understand how/what to do to successfully adhere and ensure the pills' effectiveness. Those that exhibit lower levels of health literacy should be provided with additional resources related to taking the pill correctly. Subsequently, it is hoped that by increasing health literacy levels, adherence to the oral contraceptive pill will be improved.

Chapter 6: A Simple Intervention Using Cues and Knowledge to Improve Adherence for Taking the Oral Contraceptive Pill in Australian Females

Introduction to Chapter 6

In the previous chapter I identified variance in adherence to the oral contraceptive pill, such that some people reported perfect adherence and others reported below average adherence. Subsequently, I now knew there was variability in adherence and that this population would be a suitable target for an intervention aimed at improving adherence. In the previous chapters (Chapters 2, 3 and 4) I identified that behavioural prepotency, particularly that of cues, was important in medication adherence. In Chapters 4 and 5 I also identified the importance of having knowledge regarding the specific medication or disease in predicting adherence.

Therefore, in this chapter I created and trialled a simple intervention aimed at increasing adherence to the oral contraceptive pill focussing on manipulating cues and/or knowledge related to the pill to explore which determinants (i.e., a psychological determinant or a social determinant) would lead to behaviour change. This chapter focuses on one factor from Temporal Self-Regulation Theory, rather than multiple, to ensure the intervention is not too complex and that it is simple enough for participants to engage in and incorporate into their daily lives. As many of the current interventions aimed at improving adherence are complex and aim to target multiple predictors (Nieuwlaat et al., 2014), I decided to only target one Temporal Self-Regulation Theory variable and another variable not part of the theory, but that has shown to be important in adherence in previous chapters.

Furthermore, given the previously identified measurement issues throughout the previous chapters, with regards to measures of adherence being categorised as attitudes/beliefs-based or behaviour based, I again used two self-report subjective measures of adherence to the pill (Medication Adherence Report Scale and the Timeline Follow-Back), both of which had shown advantages and disadvantages as measures in the previous chapters. This was done in an attempt to explore any possible differences in the findings and to determine whether these measures performed similarly in this population. As the Timeline Follow-Back presented some issues in the previous chapter regarding how participants entered their data, and thus it was unable to be included in analysis, some additions were made. Firstly, the instructions were slightly edited to make it clear to participants how the measure were to be completed and secondly, an example of the completed measure was also included to guide participants.

Author	Contribution	I acknowledge that these represent my contribution to the above research output Signed:
Caitlin Liddelow	Development of research question, data collection, data management, data analysis, interpretation of results, and manuscript preparation, reviewing and editing of drafts.	
Barbara Mullan	Assisted with development of research question, interpretation of results and manuscript preparation, reviewing and editing of drafts.	
Mark Boyes	Assisted with development of research question, interpretation of results and manuscript preparation, reviewing and editing of drafts.	

Abstract

Non-perfect adherence to the oral contraceptive pill ("the pill") reduces its effectiveness only 91%. Perfect adherence is imperative to ensure the prevention of pregnancy. Previous research has identified the importance of cues and knowledge in facilitating medication adherence. A full factorial simple behaviour change intervention was developed to increase adherence to the pill (primary outcome) as well as increase habit strength for taking the pill and the use of cues (secondary outcomes). A sample of young Australian females ($N = 81$, $M_{\text{age}} = 25.09$, $SD = 3.43$) who self-identified as finding it difficult to remember to take the pill were randomly assigned to four intervention conditions: 1) a control group, 2) receiving a Consumer Medicine Information leaflet about the pill, 3) implementing a daily cue to associate with taking the pill, and 4) receiving both the information leaflet and instructions to implement a cue. At baseline and six weeks, participants completed measures of adherence to the pill using two measures, habit strength, and cues. Mixed-model ANOVA's revealed no significant changes in adherence to the pill across conditions, over time. However, habit strength increased over time regardless of the condition. Participants that only received the information leaflet reported the greater change in habit strength. The presence and influence of physical cues significantly increased in the condition receiving both the information and cues, but this did not correspond with increased adherence. These findings suggest participating in an intervention, regardless of condition, may make the taking the pill more salient and thus increase 'habit' for taking the pill throughout the intervention period. It also suggests that trying to change behaviour for a non-novel behaviour is difficult and that

clinicians need to offer adherence strategies to patients when first prescribing the pill, to ensure adherence.

Introduction

According to the United Nations (2015), the oral contraceptive pill (otherwise known as “the pill”) is the most commonly used method of contraception in developed countries, with an estimated one-third of Australian females between 16-49 years currently taking it (Richters et al., 2016). In addition, it is expected that nearly 80% of females will use the pill at some stage in their life (Richters et al., 2003). Perfect adherence to the pill results in it being 99.7% effective at preventing pregnancy, however with typical adherence (e.g., missing doses or not taking at the same time every day), the effectiveness of the pill is reduced to 91% (Trussell, 2011). Studies have shown that perfect adherence (taking at the same time, every day) is rare, with approximately 50% of females missing a dose of their pill at least once a month (Molloy et al., 2012; Rosenberg et al., 1998).

One way to improve adherence to the pill may be through making the behaviour habitual. Previous research in adherence has shown a significant positive association between habit strength and medication adherence (Hoo et al., 2019). More specifically, those who report a stronger habit for taking the pill are therefore more adherent to it (Murphy et al., 2018). Most people think of a habit as a behaviour or action that we do every day with little thought (Gardner, Lally, et al., 2012), however, a habit can more rigorously be defined as an action that is automatically triggered in response to a contextual cue, such that it is a learnt automatic response (Wood & Rünger, 2016). For an action to become a habit, the action needs to be repeated in a consistent context as the result of experiencing a cue (Gardner, Lally, et al., 2012). For example, taking the pill (action) when you wake up (contextual cue) is an example of a habitual

behaviour. After consistent repetition of this combination of an action and cue, it is expected that the action will subsequently become context-dependent and thus, over time the cue will automatically elicit the action, without conscious effort (Gardner et al., 2011). Thus, there tends to be a significant association between the presence of cues and behavioural engagement, such that research has shown forming a cue-behaviour association and plan facilitates habit formation (Fleig et al., 2013, 2017).

The importance of cues in predicting engagement in healthy and unhealthy behaviours has recently been shown in previous research, such as exercise in older adults (Chou & Wister, 2005), engagement in binge drinking episodes (Murray & Mullan, 2019), teeth flossing (Judah et al., 2013) and food safety behaviours (Mullan et al., 2014). Cues have also been identified as an important construct in some health psychology theories, such as the health belief model (Rosenstock, 1974) and Temporal Self-Regulation Theory (Hall & Fong, 2007). Cues to action were initially broadly classified into two domains: internal and external cues, however more recently they have been more narrowly classified into five domains: physical, sensory, social, internal and emotional cues (Booker & Mullan, 2013; Mullan & Novoradovskaya, 2018).

More specifically, cues are often identified as being important predictors of medication adherence in qualitative studies (Kelly et al., 2014), however, have only recently begun being explored using quantitative research methods. Two studies using self-report questionnaires showed that cues, specifically contextual cues and only having one or two cues, identified

significant associations between the presence of cues and medication adherence (Liddelow, Mullan, & Boyes, 2020b; Stawarz et al., 2016).

The importance of cues in medication have also been experimentally explored, but in very few studies (e.g., Rigsby et al., 2000; Rosen et al., 2004). Rosen and colleagues (2004) applied 'cue-dose training' to a group of adults taking metformin, a type of oral medication used to treat type 2 diabetes. The intervention involved participants linking taking their medication to a daily activity, such as brushing teeth or at a specific mealtime. Results showed that participants who effectively linked their medication-taking to another daily activity improved their adherence by approximately 15% compared to the control group (Rosen et al., 2004). Therefore, further research into the role of cues using experimental research is warranted, to fully understand its ability to facilitate adherence behaviour. As perfect adherence to the pill is imperative to ensure its success in preventing pregnancy, exploring the possibility of pairing the pill with a daily cue may be a promising avenue to explore in attempts to make taking the pill habitual, and in turn improve adherence.

However, research suggests that behaviours (such as taking medication) may be more difficult to become habitual if the reward for doing the behaviour is distal (Mullan & Novoradovskaya, 2018). In the case of the pill, females may not experience the benefit of the pill unless they are engaging in unsafe sexual practices where the risk of becoming pregnant is high. Thus, taking the pill may be more difficult to become a habit because the 'benefit' is not experienced immediately. Due to this, it is important to explore other ways in which adherence to the pill can be improved that do not involve making the behaviour a habit.

One relatively easy method that has shown to be associated with better medication adherence is through educating participants using credible sources and information. Having a greater level of understanding of medications and their usage has shown to be linked to greater adherence (Al-Qazaz et al., 2011; Mekonnen & Gelayee, 2020). Research exploring this association with adherence to the pill has also shown that greater knowledge/understanding of the pill, its uses, mechanisms of action and side effects are positively associated with better adherence and continuation of the pill (Hall et al., 2014; Liddelow, Mullan, & Boyes, 2020a). Therefore, the potential of increasing knowledge through providing information from credible sources, as a mechanism for improving adherence to the pill, lends itself to being further explored. It may be that a greater understanding of the pill and how to take it effectively will increase adherence. By identifying ways to improve adherence to the pill, whether it be through the use of cues or increased knowledge, we will hopefully be able to provide strategies to most efficiently adhere and ensure the pill's greatest effectiveness.

The Present Study

This study aimed to design an experiment to explore two different manipulations that were hypothesised to increase adherence, namely knowledge and habit. Using a 4 (intervention condition) x 2 (time points, pre and post) full factorial design we recruited people who menstruate who self-identified as not very good at remembering to take the pill and measured their adherence to the pill over six weeks. The design of this intervention is based on a recent successful simple intervention aimed to increase the use of reusable coffee cups (Novoradovskaya, Mullan, Hasking, et al., 2020), which can also

be considered a one-step distal behaviour similar to that of taking the pill. The four intervention conditions are outlined below:

Group 1 – Control. The control group were provided with no intervention content and were simply instructed to take their pill at the same time every day as per the usual instructions given by their health professional.

Group 2 – Information Only. The information only group was provided with a standardised and general Consumer Medicine Information leaflet, much like the ones provided in the packet/box (see Appendix S). These leaflets provide the consumer with information regarding how the pill works, how to take it correctly, any potential side effects, and what to do if a dose is missed. A Consumer Medicine Information leaflet was provided for both the combination pill and the progestogen-only pill (mini-pill) and participants randomised to this group were instructed to select the one that matched their current pill to ensure they were receiving the correct information for their pill type. Participants were instructed to try and take their pill for the next 6 weeks according to the information in the leaflet. The intervention content provided uses three behaviour change techniques ‘instruction on how to perform the behaviour’, ‘information about health consequences’, and ‘credible source’ (Michie et al., 2013).

Group 3 – Cue Implementation Only. Participants in this group were provided with a definition of a cue and asked to spend the next few minutes thinking of a cue they can match/associate with taking their pill to assist them in remembering to take it. Participants were told the cue must be something they do every day and were provided with examples, such as ‘placing your pill box on your bedside table so you see it every morning when you wake up’.

They were then instructed to write down their chosen cue and to ensure they take their daily pill when they see or experience this cue for the next 6 weeks. The intervention content provided uses three behaviour change techniques ‘prompts/cues’, ‘behavioural practice/rehearsal’, and ‘habit formation’ (Michie et al., 2013).

Group 4 – Information + Cue Implementation. Participants in the combined information and cue implementation group received the same intervention material from groups 2 and 3. Participants were instructed to read the Consumer Medicine Information leaflet for their specific pill and then asked to choose a cue to assist them to take their pill every day (preferably at the same time). The intervention content provided uses the six behaviour change techniques mentioned previously.

Subsequently, based on previous research in medication adherence (Liddelow, Mullan, & Boyes, 2020b, 2020a) and habit theory (Gardner et al., 2011), as well as the four intervention conditions outlined above, it was hypothesised:

1. There will be a positive association between (i) pill habit strength and pill adherence and, (ii) pill habit strength and influence of cues at follow-up.
2. Participants who match their pill-taking behaviour with their choice of a daily cue (cue implementation only group and combined group) will report an increase in habit strength, pill adherence and influence of cues for taking the pill over time compared to the groups without a cue.

3. Participants in the cue implementation only group will report a greater increase in habit strength, pill adherence and influence of cues, compared to the control group, information only group and combined group.
4. It is expected that at the end of six weeks, there will have been an increase in the primary outcome variable (adherence to the pill) and the two secondary outcome variables (habit and cues) in all three intervention groups, but not the control group.

Methods

Intervention Content

The intervention comprised of four groups, with three groups receiving intervention content and a fourth group, the control, who received no intervention. Each intervention group received a different combination of content based on what has been shown to be important in previous research related to medication adherence and adherence to the pill (Liddelow, Mullan, & Boyes, 2020b). Specifically, each group received a behaviour change technique (BCT; Michie et al., 2013) or a combination of techniques to evoke improvements in adherence, such as BCT 'prompts/cues'.

Measures

Habit

Habit strength was measured using the Self-Report Habit Index (Verplanken & Orbell, 2003). This measure is the most widely used measure of habit strength and consists of the prompt "Ensuring I take my oral contraceptive pill correctly is something..." followed by 12 statements such as

“...I do frequently” and “I do without thinking”. Participants were asked to select how much they agree or disagree with each statement on a 7-point Likert scale from *1 = strongly disagree* - *7 = strongly agree*. The scores from each item were combined and the mean score identified. Higher mean scores indicated a higher habit strength for taking the pill. This measure showed good to excellent internal consistency in this sample ($\alpha = .89$ at baseline to $.93$ at follow-up). See Appendices U and V for the full survey measures.

Cues

The presence and influence of cues on adherence to the pill were measured using the Cues to Action Scale (Booker & Mullan, 2013), which has been widely used in health behaviour research (Liddelow, Mullan, & Boyes, 2020b; Moran & Mullan, 2020; Murray & Mullan, 2019). This measure consists of five types of cues namely, physical, sensory, social, internal, and emotional cues. For each subscale, participants were first asked “Are there any physical things in the environment which trigger you to take your medication?”, which is answered dichotomously (*1 = yes, 2 = no*). If participants respond ‘yes’ to this question they are then presented with two related questions; one related to the frequency of experiencing these types of cues, from *0 = never* - *7 = a few times a day*, and another question related to how influential the cues are at eliciting their behaviour, from *0 = not at all likely* - *6 = every time*. If participants select 'No' for the first question of each subscale, they subsequently receive a subscale score of zero. If participants select 'Yes' for the first question, questions two (frequency) and three (influence) are multiplied to give an overall subscale score. The mean of all five subscales is used as the overall score for this measure, with higher scores

indicating participants not only experience more types of cues but that these cues are also influential in their behaviour.

Adherence to The Pill

Adherence to the pill at both baseline and follow-up was measured using two different self-report measures, as previous research has identified different measures of adherence measure different things, such as attitudes/beliefs or actual behaviour, and thus perform differently in research (Liddelow, Mullan, & Boyes, 2020b).

Medication Adherence Report Scale (Horne & Weinman, 1999).

The five-item Medication Adherence Report Scale is a widely used measure of adherence and has previously been used to measure adherence to the pill (Liddelow, Mullan, & Boyes, 2020a; Molloy et al., 2012). It contains five questions related to medication-taking over the previous two weeks, that are summed. For example, “I decided to miss out a dose of my pill”, all of which are answered on a 5-point Likert scale ranging from *1 = never* to *5 = always*. All items are reversed scored such that higher scores indicate better adherence. This measure showed adequate internal consistency in this sample ($\alpha = .71$ at follow-up to $.74$ at baseline).

Timeline Follow-Back (Sobell & Sobell, 1992). The second measure of adherence was an adapted version of the Timeline Follow-Back which has previously been used in studies of medication adherence (Liddelow, Mullan, & Novoradovskaya, 2020; Liddelow, Mullan, & Boyes, 2020b). This measure of adherence is presented in a calendar-like form to prompt participants to recall their previous week and to think about each day individually. Participants are instructed to enter the day and date, starting from the day before and working

backwards. They are also asked to enter any special events that may have occurred on these individual days. The next two parts ask participants to indicate whether or not they took their pill on that day by entering a Y (for yes) or an N (for no). The final row of the measure asks participants if, on that day, they took their pill as prescribed (typically, at the same time every day) by entering a Y or N. If participants did not take their pill that day, a response of N is expected. Participants received a total adherence score out of 14 (one score for each day taking the pill and another score if the pill was taken correctly), with higher scores indicating better adherence over the previous week. If participants did not take their pill on an individual day, they automatically got zero for that day.

Demographics

Participants were asked to complete 11 demographic questions, most of which related to which type of pill they were currently taking, how long they have been on the pill, whether they were sexually active, had previous pregnancies and/or children, and their use of emergency contraception. General demographics such as age, gender identity, education and ethnicity were also collected.

Participants and Procedure

Advertisements for participation in the study were placed on social media sites such as Facebook, Twitter, and Reddit, between May and September 2020. To participate, participants had to be between the ages of 16 and 35 years, currently taking the pill for contraception (prevention of pregnancy) and self-perceived themselves as being poor at remembering to take their pill. If interested, participants clicked on the link, which directed

them to an online Qualtrics survey. After reading the participant information sheet, participants were asked to give consent by checking Yes or No to the question "Do you understand everything in the participant information sheet and consent to participate in this study?". If 'No' was selected, they could not continue the study. Upon giving informed consent, participants entered their email address and create a unique code to assist the researchers in linking their baseline and follow-up responses. After this, participants completed all baseline measures, which took no longer than 20 minutes, and were then randomly, assigned to one of the four groups using the built-in random number generator setting in Qualtrics and were blind to what the other groups were. The Qualtrics randomiser setting monitors the randomisation to ensure participants are allocated based on a 1:1 ratio, but in a random order. After completing the intervention, they were advised they would receive a follow-up email in six weeks. After the six weeks had elapsed, participants were sent an email asking them to complete the follow-up, with a link to the Qualtrics survey. Upon entering their unique code, participants completed the same set of measures as at baseline. Participants who fully completed both parts were placed in a prize draw to win 1 of 5 shopping vouchers valued at \$50 each. The University's Human Research Ethics Committee approved the study. An *a*-priori power analysis was conducted to see the minimum number of participants needed to detect a small-medium effect size ($f = 0.25$), with $\alpha = .05$, power = 0.80, four groups and two-time points, a minimum sample size of 48 (12 per group) was needed. However, accounting for at least 30% attrition at each time point over the six weeks, we aimed to recruit 80 participants in total (20 per group).

Data Analysis

The data collected at both time points were combined and analysed using SPSS Version 26 (IBM Corp, 2019). To explore possible differences in baseline demographics and key variables (adherence, habit, and cues) between those who completed both time points and those who did not, Chi-Square Test of Contingencies and independent samples *t*-tests were used. To investigate whether randomisation was successful, a one-way Analysis of Variance (ANOVA) was conducted. Bivariate correlation coefficients (Pearson's) were conducted to assess the relationships between each variable at (i) baseline, (ii) follow-up and (iii) overall at baseline and follow-up. For the main analysis, adherence to the pill was the primary outcome and habit strength and cues were the secondary outcomes. A 4 x 2 (intervention condition x time) repeated measures between groups ANOVA (mixed model) was used to examine the changes in adherence, habit strength and cues between baseline and follow-up for each of the four groups. If the interactions from these mixed-model ANOVA's were significant, one-way ANOVA's would be used to examine the differences between groups on each of the outcome variables at the two-time points.

Results

Participants

Initially, 358 participants responded to the advertising material, however, 225 of these did not complete the baseline questionnaire and thus were not randomised to a group. This left a total of 153 participants who completed the baseline questionnaire and were randomised to a group. A total

of 72 participants did not complete the follow-up, with two of these not supplying an email address to be contacted to receive the link to the follow-up. Eighty-one participants completed both time points, and their data was subsequently used in the analysis (see Figure 6.1 for a flow chart of participants). There were no significant differences between completers of both time points and non-completers on any demographics or key variables at baseline assessment.

Of those that completed both parts ($N = 81$), all participants identified as female and their ages ranged between 18 and 34 years ($M_{\text{age}} = 25.09$, $SD = 3.43$). The sample was highly educated with 62.8% ($n = 51$) having a bachelor's degree or higher. A total of 85.2% ($n = 69$) of the sample also identified as Caucasian. The large majority 82.7% ($n = 67$) reported currently using the combined pill (one-month cycle), 11.1% ($n = 9$) using the combined pill (13-week cycle) and the remaining 6.2% ($n = 5$) were currently using the progestin-only pill, or the 'mini-pill'. The length of time taking the pill ranged from 1 month to 16 years ($M = 7.11$ years, $SD = 4.12$), with 66.6% ($n = 54$) having been recommended the pill by their General Physician or Gynaecologist. Only 7.4% ($n = 6$) of participants had children and 19.8% ($n = 16$) reported ever being pregnant. Just over half of the sample, 54.3% ($n = 44$) reported having ever used emergency contraception. See Table 1 for the baseline demographic characteristics of each group and overall.

Overall, participants reported reasonably high adherence at baseline, particularly when using the Medication Adherence Report Scale (MARS-5) with $M = 22.69$ out of a possible 25. Adherence, as measured by the Timeline Follow-Back, indicates that, on average, participants are adherent between 4-5

days a week. However, habit strength overall was average with $M = 3.93$ out of a possible 7 (see Table 6.1 for the descriptive statistics of each group and overall, at both time points).

Figure 6.1

Flow Chart of Participants

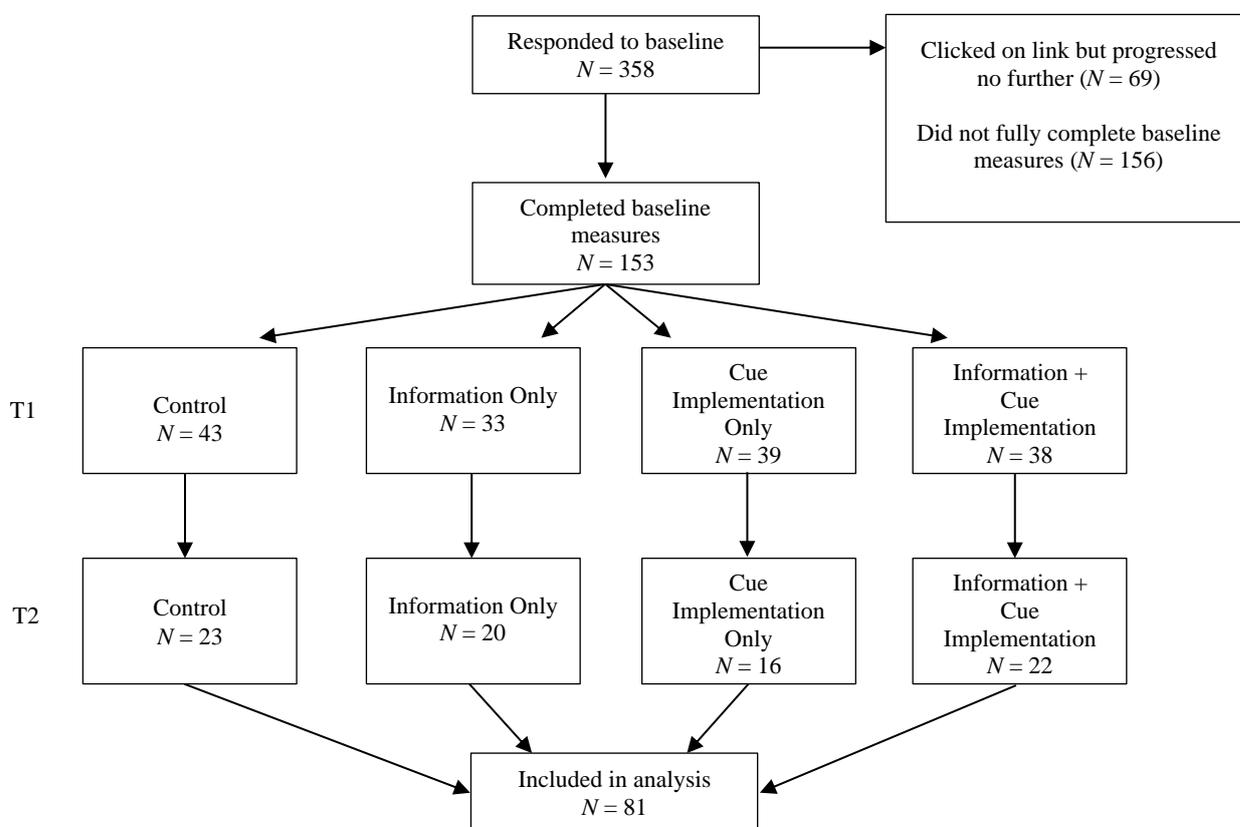


Table 6.1*Baseline Demographic Characteristics Between Groups and Overall*

	Control (<i>n</i> = 23)	Information Only (<i>n</i> = 20)	Cue Implementation Only (<i>n</i> = 16)	Combined (<i>n</i> = 22)	Total (<i>N</i> = 81)
	Mean ± SD / <i>n</i> (% group)	Mean ± SD / <i>n</i> (% group)	Mean ± SD / <i>n</i> (% group)	Mean ± SD / <i>n</i> (% group)	Mean ± SD / <i>n</i> (% group)
Age	25.43 ± 3.82	24.85 ± 2.96	26.44 ± 3.83	23.95 ± 2.87	25.09 ± 3.43
Type of pill					
Combination	22 (95.7)	17 (85.0)	15 (93.8)	22 (100.0)	76 (93.8)
Mini-pill	1 (4.3)	3 (15.0)	1 (6.3)	0 (0.0)	5 (6.2)
Education					
≤ Secondary school	4 (17.4)	8 (40.0)	5 (31.3)	7 (29.2)	24 (29.6)
Bachelor's degree	15 (65.2)	7 (35.0)	10 (62.5)	13 (59.1)	45 (55.6)
≥ Master's degree	4 (17.4)	5 (25.0)	1 (6.3)	2 (9.1)	12 (14.8)
Ethnicity					
Caucasian/European	19 (82.6)	17 (85.0)	15 (93.8)	19 (86.4)	70 (86.4)
Asian/Middle Eastern	3 (13.0)	3 (15.0)	1 (6.3)	2 (9.1)	9 (11.1)
Indigenous Australian	1 (4.3)	0 (0.0)	0 (0.0)	1 (4.5)	2 (2.5)

Note. SD = standard deviation, MARS-5 = Medication Adherence Report

Scale, TLFB = Timeline Follow-Back

Randomisation Check

We compared the means of key variables at baseline for each of the four intervention groups using a one-way ANOVA. No significant differences between groups were identified on age, the number of children, habit strength, cues or either of the measures of adherence to the pill. We also compared

differences in categorical demographic variables (type of pill, ethnicity, and education level) and also found no significant differences between the groups.

Associations Between Variables

Bivariate Pearson's correlations were computed to assess the strength of the association between the main variables of interest (see Table 6.2 for the bivariate correlations of age, length of time using the pill and the variables of interest at baseline and follow-up). At follow-up, there were significant positive correlations between habit strength for taking the pill and adherence using both measures; Medication Adherence Report Scale ($r = .464, p < .001$) and the Timeline Follow-Back ($r = .377, p < .001$), but there was no significant association between habit strength and cues ($r = -.139, p = .728$), which is unexpected.

Table 6.2

Bivariate Correlations (Pearson's) at Baseline (T1) and Follow-up (T2) – N = 81

	Age	Length of time using	MARS- 5 T1	TLFB T1	Habit T1	Cues T1	MARS- 5 T2	TLFB T2	Habit T2	Cues T2
Age	-									
Length of time using	.640**	-								
MARS-5 T1	.045	-.110	-							
TLFB T1	.131	.048	.441**	-						
Habit T1	-.070	-.025	.442**	.280**	-					
Cues T1	.141	-.020	.144	.138	.130	-				
MARS-5 T2	.015	-.090	.442**	.144	.354**	.150	-			
TLFB T2	.007	-.140	.106	.156	.187	.102	.505**	-		
Habit T2	.001	-.023	.239*	.217	.607**	.132	.464**	.377**	-	
Cues T2	-.027	-.057	.014	-.075	-.018	.473**	.115	.108	.039	-

Note. MARS-5 = Medication Adherence Report Scale, TLFB = Timeline

Follow-Back

** $p < .001$, * $p < .05$

Effects of the Intervention: Mixed Model ANOVA

A 4 (intervention condition) x 2 (time) mixed-model ANOVA was conducted to assess the change in adherence to the pill (using both measures), habit strength, and cues between the four intervention groups over time (see Table 6.3 for the mixed-model ANOVA results).

Primary Outcomes

Adherence: Medication Adherence Report Scale (MARS-5). A

significant main effect for time was not identified $F(1, 77) = 0.01, p = .927$, partial $\eta^2 = .00$ meaning there was no change in adherence to the pill over time using this measure. There was also no significant main effect of intervention group identified $F(3, 77) = 0.78, p = .507$, partial $\eta^2 = .03$, and no significant interaction between time and intervention group $F(3, 77) = 2.10, p = .108$, partial $\eta^2 = .08$.

Adherence: Timeline Follow-Back. A significant main effect for time

was not reported $F(1, 77) = 0.51, p = .479$, partial $\eta^2 = .01$ and a significant main effect for intervention group was also not identified $F(3, 77) = 1.22, p = .308$, partial $\eta^2 = .05$. A non-significant interaction between time and intervention group was reported $F(3, 77) = 2.41$, partial $\eta^2 = 0.08$. Examination of the means showed that three of the intervention groups (control, information only and the combined group) produced increases in adherence to the pill over time. The combined group produced the largest change in adherence from baseline to follow-up. The cue only group, however, reported a decrease in adherence from baseline to follow-up.

Secondary Outcomes

Habit. A significant main effect for time was identified $F(1, 77) =$

$10.59, p = .002$, partial $\eta^2 = .12$. No significant main effect for intervention group was identified $F(3, 77) = 2.69, p = .052$, partial $\eta^2 = .10$. In addition, a significant interaction between time and intervention group was identified, $F(3, 77) = 2.81, p = .045$, partial $\eta^2 = .10$, such that habit strength increased in all groups over time.

Cues. A significant main effect for time was not reported $F(1, 77) = 0.46, p = .499, \text{partial } \eta^2 = .01$. A significant main effect for intervention group was not identified $F(3, 77) = 0.20, p = .900, \text{partial } \eta^2 = .01$. The interaction between time and intervention group was non-significant $F(3, 77) = 2.60, p = 0.58, \text{partial } \eta^2 = .09$. Examination of the means showed two intervention groups increased in the number and influence of reported cues (cue only group and the combined group) over time, however, the control and information only groups both decreased in the number and influence of reported cues from baseline to follow-up.

A mixed-model ANOVA was also conducted only using the physical cues subscale of the cues to action measure, as physical cues have shown to be the most salient in medication adherence behaviours. A significant main effect for time was not identified $F(1, 77) = .005, p = .943, \text{partial } \eta^2 = .00$. A significant main effect for intervention group was also not identified $F(3, 77) = 0.365, p = .778, \text{partial } \eta^2 = .01$. However, a significant interaction between time and group was reported $F(3, 77) = 3.89, p = .012, \text{partial } \eta^2 = .13$ such that the presence and influence of physical cues increased over time in the two groups that implemented a cue (cue implementation only and combined groups), whereas the control and information only groups both experienced a decrease.

Table 6.3*Results of the Mixed-Model ANOVA for Each Outcome Variable*

Outcome		<i>F</i>	<i>df</i>	<i>p</i> -value	Partial eta squared
Habit strength	Main effects				
	Time	10.59	1	.002*	0.121
	Group	2.69	3	.052	0.095
	Interaction				
	Time x Group	2.81	3	.045*	0.099
Cues	Main effects				
	Time	0.46	1	.499	0.006
	Group	0.20	3	.900	0.008
	Interaction				
	Time x Group	2.60	3	.058	0.092
MARS-5	Main effects				
	Time	0.01	1	.927	0.000
	Group	0.782	3	.507	0.030
	Interaction				
	Time x Group	2.10	3	.108	0.076
TLFB	Main effects				
	Time	0.51	1	.479	0.008
	Group	1.22	1	.308	0.053
	Interaction				
	Time x Group	2.41	3	.075	0.100

Note. MARS-5 = Medication Adherence Report Scale, TLFB = Timeline

Follow-Back

* $p < .05$

Effects of the Intervention: Differences Between Intervention Groups

A one-way between-groups ANOVA was performed to explore how the intervention groups differed at follow-up on the secondary outcome variables of habit and physical cues. These were the only outcome variables that reported significant time x group interaction. A difference between groups in habit strength $F(3, 77) = 4.14, p = .009$ was evident at follow-up. Post-hoc analysis using Turkey's HSD indicated that the information only group had significantly higher habit strength compared to the control group ($p = .010$), and the cue implementation only group ($p = .043$). There were no significant differences between groups at follow-up on the presence and influence of physical cues, $F(3, 77) = 1.54, p = .212$.

A one-way between-groups ANOVA was performed to explore the change in habit strength and physical cues scores from baseline to follow-up between each of the intervention groups. A change score was created for each variable. A significant difference in change of habit strength over time was identified between the groups $F(3, 77) = 2.81, p = .045$, as well as a significant change in physical cues over time between the groups $F(3, 77) = 3.89, p = .012$. Post-hoc analysis using Tukey's HSD indicated the information only group experienced a significantly greater change in habit strength compared to the control group ($p = .042$), and the combined group experienced a significantly greater change in the presence and influence of physical cues compared to the control group ($p = .030$). See Table 6.4 for the descriptive statistics of each group at both time points and the one-way between-groups ANOVA results.

Table 6.4

Descriptive Statistics of Each Group at Both Timepoints and The One-Way Between Groups ANOVA Results (N = 81)

Variable	Time	Control	Information	Cue	Combined	Total	F	p-value
		(n = 19)	Only (n = 8)	Implementation Only (n = 9)	(n = 13)	(n = 49)		
		Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD		
MARS-5 (2 weeks)							2.10	.108
	Baseline	22.48 ± 2.13	23.20 ± 1.64	22.88 ± 2.63	22.64 ± 2.75	22.78 ± 2.29		
	Follow-up	23.21 ± 1.99	23.40 ± 2.01	21.63 ± 3.80	23.18 ± 2.32	22.90 ± 2.54		
TLFB (1 week)							2.41	.075
	Baseline	10.19 ± 3.88	11.82 ± 2.68	12.27 ± 2.05	9.80 ± 4.46	10.81 ± 3.65		
	Follow-up	11.52 ± 2.27	12.59 ± 2.00	9.91 ± 5.22	11.60 ± 3.35	11.55 ± 3.21		
Habit strength							2.81	.045*
	Baseline	3.71 ± 1.25	4.05 ± 0.9	3.66 ± 1.03	4.18 ± 1.14	3.91 ± 1.12		
	Follow-up	3.80 ± 1.09	4.99 ± 1.33	3.90 ± 1.11	4.41 ± 1.28	4.28 ± 1.28		
Cues							2.60	.058
	Baseline	34.13 ± 20.58	37.45 ± 28.16	26.06 ± 19.39	24.68 ± 21.77	30.79 ± 23.00		
	Follow-up	34.13 ± 20.58	29.30 ± 31.23	32.31 ± 20.86	35.77 ± 24.35	32.49 ± 25.05		
Physical cues							3.89	.012*
	Baseline	20.61 ± 13.12	20.90 ± 13.12	19.63 ± 15.73	14.45 ± 16.42	18.81 ± 14.66		
	Follow-up	15.26 ± 13.62	16.05 ± 15.54	23.69 ± 13.42	21.05 ± 14.15	18.69 ± 14.36		

Note. SD = standard deviation, MARS-5 = Medication Adherence Report Scale, TLFB = Timeline Follow-Back, * $p < .05$

Discussion

A full factorial simple intervention was conducted to identify the mechanisms to improve adherence to the pill over six weeks. Two different manipulations, namely habit (through the use of cues) and information/knowledge, were hypothesised to improve medication adherence, based on previous literature (Lally & Gardner, 2013; Liddelow, Mullan, & Boyes, 2020a, 2020b).

Primary Outcome - Adherence

There were no significant intervention effects identified on either measure of the primary outcome of medication adherence, such that there were no significant increases in adherence over time, meaning the intervention was unsuccessful in changing behaviour. One possibility for this is that the chosen behaviour, adherence to the pill, was not a novel behaviour for the participants and thus it was more difficult to elicit changes in behaviour. This is further reinforced by the possible ceiling effect in adherence, where both measures reported high levels of adherence to the pill, thus leaving little room for improvement despite targeting people who believed they were poor at adhering. The intervention this study was modelled on identified significant improvements over time in the use of a reusable coffee cup (Novoradovskaya, Mullan, Hasking, et al., 2020), however, the participants in this study had never used a reusable coffee cup before and thus the behaviour was novel. This finding has also been identified in other interventions that introduce a novel behaviour (Keller et al., 2021; Mergelsberg et al., 2020; Mullan et al., 2014). It is possible that for cue-behaviour associations to be effective, they need to be novel and thus clinicians should therefore ensure they are providing patients

with strategies for adherence (e.g., the use of cues) when prescribing the pill initially to ensure this cue-behaviour association elicits adherence.

This finding also suggests that neither the use of a cue nor providing information was able to change behaviour. Behaviour change techniques aimed to change behaviour were included, but it appears that neither of these techniques were successful at eliciting change in the behaviour but rather just changes in the underlying mechanisms of the behaviour (e.g., habit). Perhaps future research needs to take a step back and first better understand the specific malleable predictors of adherence to the pill before applying BCTs in attempts to improve it.

Secondary Outcome – Habit

The findings showed a significant positive association between habit strength for taking the pill at follow-up and adherence using both self-report measures at follow-up. This is consistent with recent research which has found an association between habit and medication adherence generally (Badawy et al., 2020; Liddelow, Mullan, & Boyes, 2020b) and more specifically to the pill (Murphy et al., 2018). Furthermore, it was demonstrated that all groups experienced an increase in their habit strength from baseline to follow-up, which has also been shown in other interventions that use mechanisms of habit formation (Bartle et al., 2019; Novoradovskaya, Mullan, Hasking, et al., 2020; Rompotis et al., 2014) and is in line with some theories of behaviour change, such as Temporal Self-Regulation Theory (Hall & Fong, 2007). This finding suggests that simply participating in an intervention has the ability to increase good habits, regardless of the condition.

Interestingly in this study, the largest change over time in habit strength was in the information only group, which suggests those who are provided (and presumably read) the Consumer Medicine Information leaflet about the pill developed stronger habits for taking it. This is consistent with previous qualitative research which identified the importance of knowledge in assisting with adherence to medications (Liddelow et al., 2020). However, our sample was highly educated and thus likely to have higher levels of health literacy (Adams et al., 2009; Heijmans et al., 2015), which is the ability to find, understand and use health information (Sørensen et al., 2012) and have shown to be important in adherence to the pill (Liddelow, Mullan, & Boyes, 2020a), such that those with greater health literacy also have better adherence. Therefore, it appears that in a highly educated population, the use of knowledge to increase habit strength for a healthy behaviour does work. Interventions for similar behaviours should therefore consider making them simpler, and perhaps consider the use of fact sheets and if medication-related, Consumer Medicine Information leaflets. Health professionals prescribing the pill should also spend more time with patients when first prescribing, to ensure they fully comprehend how the pill works and how to adhere.

Although there were increases in habit strength across all conditions, these changes did not translate into behaviour change. One possible explanation for this is that although habit strength increased, it may not have been enough for the behaviour to become ‘habitual’ and thus actually influenced by habit. According to Lally and colleagues (2010), a habit can take anywhere from 18 to 254 days to form and a more recent study found it takes a median of 59 days (8 weeks) for a behaviour to reach peak automaticity (Keller

et al., 2021). As the pill is a distal benefit behaviour and the benefits of taking it are not experienced immediately (Collins & Mullan, 2011; Mullan & Novoradovskaya, 2018), it may take longer for the behaviour to become habitual. Future research should consider extending the intervention period from 6 weeks to perhaps 24 weeks, to explore whether this increased measurement time sees more significant changes in habit strength and subsequently adherence to the pill. Conversely, given that participants were already taking the pill for some time, they likely already had some sort of routine for taking the pill, and thus a degree of ‘habit’, which may have been disrupted by this intervention. Therefore, future research may consider recruiting participants who are only just beginning to use the oral contraceptive pill and monitoring/assessing their habit strength for taking the pill over a period of many weeks.

Secondary Outcome - Cues

There was no significant condition by time interaction for cues overall, but there were significant differences between groups over time on the presence and influence of physical cues, alone. More specifically, the combined group significantly reported an increase over time in the number and/or experience of physical cues. This is not surprising given participants in this group were told to choose a cue to match with their pill-taking behaviour, however, what is unexpected is that this group did not report an increase in adherence. A probable explanation for this finding is that previous research has shown having one or two cues is predictive of adherence, but anything more than this and adherence can become worse (Liddelow, Mullan, & Boyes, 2020b). Another possibility is due to the lack of association between cues and

habit strength at both baseline and follow-up in this study. If two factors are not related, it is highly unlikely that changes in one factor will result in changes in the other. It is suggested that at baseline, future research ensures participants are asked if they already use a cue to assist their adherence and if so, to continue using this to ensure the salience of that specific cue rather than adding another cue and weakening the cue-behaviour association.

Limitations

The study is not without its limitations. Firstly, the sample was highly educated and does not reflect the general education level of young Australian females where only 42% have a bachelor's degree or higher (Australian Bureau of Statistics, 2020), and thus the findings need to be interpreted with this in mind. Secondly, adherence at baseline in all groups was reasonably high and this may also explain the lack of significant effects. Recruitment for similar studies in the future should consider other avenues for recruiting participants that may not be as good at adhering to their medication or are only just beginning to use the pill. Thirdly, the use of self-report measures, especially for variables that are deemed to occur in the unconscious, such as habit, (Hagger et al., 2015; Sniehotta & Penseau, 2012), the accuracy of the results may be limited. Similarly, self-report medication adherence measures may be open to reporting and social biases (Stirratt et al., 2015), but they were the optimal choice for this study given the online nature of the study, their ease of use, cheap cost and the ability to collect data without being face-to-face. Similarly, including a measure of oral contraceptive pill knowledge at each time point, such as the 41-item knowledge measure by Hall et al. (2013), may have given additional insight into the mechanisms of change within the intervention.

Finally, given the large body of evidence supporting the effectiveness of implementation intentions (Gollwitzer & Sheeran, 2006), future research may consider asking participants to make an implementation intention once they have identified their cue of choice.

Conclusion

The current intervention was unsuccessful in eliciting changes in adherence to the pill in Australian females. However, habit strength for the pill increased over time regardless of condition. The information only group who only received the Consumer Medicine Information leaflet was the only group to report a significant increase in habit. There was no overall change in cues, but there was a change in physical cues specifically such that those in the combined group reported experiencing an increase in the number and influence of physical cues. However, this increase in physical cues did not elicit a change significant change in adherence behaviour. The findings suggest that none of the BCT's included in the intervention were successful in changing behaviour, but rather only the underlying mechanisms of the behaviour (e.g., habit). It may be possible that participating in an intervention, regardless of the content, makes the habit for a behaviour more salient but does not act as a mechanism of change. We recommend future research considers replicating the intervention but with an extended intervention period to explore whether the changes in the underlying mechanisms can lead to changes in adherence.

Chapter 7: General Discussion

Introduction to Chapter 7

In this final chapter, I present and summarise the key research findings of the thesis. In addition, I discuss the main theoretical implications and implications for measurement. Thirdly, I detail the practical implications for intervention research and health professionals. I also examine the limitations of the thesis and directions for future research and finish with an overall conclusion.

Summary of Research Findings – Aim One

The first aim of this thesis was to investigate the applicability of Temporal Self-Regulation Theory to medication adherence. To address this aim, Chapters 2, 3 and 4 applied meta-analytic, quantitative, and qualitative research designs to explore the utility of the theory. In Chapter 2, the meta-analysis identified weak-to-moderate direct associations between all three Temporal Self-Regulation Theory constructs and medication adherence. Moderator analysis also identified differences in the strength of the associations depending on the type of medication adherence measure used. Therefore, a third aim, which was not an initial aim of this thesis, was to investigate the differences between self-report measures of medication adherence in research. In Chapter 3, the results provided partial support for the theory using a prospective design with a one-week follow-up, with cues being the only common predictor, across two different measures of adherence. I also identified differences in the findings when using the different measures, such that one measure (attitudes/beliefs based) accounted for more

variance in medication adherence compared to the other measure (measure of behaviour), suggesting the theory may be a better predictor of attitudes/beliefs, than behaviour. In Chapter 4 using a qualitative methodology, I again provided partial support for Temporal Self-Regulation Theory in medication adherence, with cues particularly important for those engaging in simple regimens and being particularly important for engagement in a more complex medication regimen. Other important factors influencing adherence were also identified such as the side-effects/symptoms of the disease, choice, and knowledge.

Theoretical Findings and Implications

The converging findings of this thesis provide partial support for the applicability of Temporal Self-Regulation Theory to medication adherence (Chapters 2, 3, and 4). The three chapters supported the individual importance of intention, behavioural prepotency, and self-regulatory capacity, which aligns with the theory and previous research which has also explored these factors in medication adherence (Hall & Fong, 2007; (Liddelow, Mullan, & Novoradovskaya, 2020; Pakpour et al., 2017; Phillips et al., 2016). Specifically, this suggests that individuals need at least one of these factors to adhere to their medication, and clinicians should strongly consider discussing some of these with patients such as planning a specific time to take the medication or linking the medication with another daily activity/routine (e.g., bedtime).

The interactions proposed by the theory were not strongly supported in this research. However, as Chapter 3 is the first study to apply Temporal Self-Regulation Theory in its entirety to medication adherence I suggest that future

research replicates this study. If the findings of this study also show little support for the interactions in the theory, it may then be important to consider applying the theory to specific populations with varying complexities associated with adherence to assess if the interactions are supported in specific populations. Populations such as those experiencing a certain disease (e.g., hypertension), those that have life-long conditions (e.g., cystic-fibrosis), or are engaging in specific medication regimens (e.g., complex regimens with a minimum of four medications), may be good populations to consider.

Similarly, it may be that the theory is not the best at explaining behaviour, and some changes should be considered. For example, previous research has shown that planning is often needed to translate intentions into behaviour (Mullan et al., 2011; Wong & Mullan, 2009), specifically for distally beneficial behaviours such as medication adherence (Hofmann et al., 2012). Therefore, perhaps planning (or self-regulatory capacity more broadly) should be included as a mediator of the intention-behaviour relationship in Temporal Self-Regulation Theory, rather than a moderator. Future research should consider testing this adapted model in medication adherence and exploring whether these interactions account for more variance in adherence.

Despite not identifying full support for Temporal Self-Regulation Theory in this research project, the theory still accounted for between 20-50% of the variance in adherence which is almost 40% more than what the theory of planned behaviour has accounted for in this behaviour previously (Rich et al., 2015). This, therefore, warrants its continued application and exploration, whether as the theory

currently is, or in a slightly adapted form, in medication adherence and other adherence-type behaviours.

Measurement Findings and Implications

All measures used throughout this thesis are not without their flaws, specifically measures of adherence. Firstly, intention was measured using two statements, however, the reliability was high, which is not unusual in research that includes intention items (Liddelow, Mullan, & Novoradovskaya, 2020; Novoradovskaya et al., 2020), and thus the use of more than one item appears to be redundant. Going forward, researchers should consider the use of a single-item measure of intention, particularly in adherence. With regards to the measurement of habit, in both society and research, there tends to be a conflation of the word 'habit' with 'routine' (Southerton, 2013). Similarly, measuring a construct that is deemed to occur in the unconscious also presents difficulties in accurate reporting (Hagger et al., 2015). This questions the validity of the Self-Report Habit Index (Verplanken & Orbell, 2003) and the 4-item automaticity subscale (Gardner, Abraham, et al., 2012) as measures of habit. As it currently stands, however, the use of these self-report measures is the gold standard for assessing habit and automaticity of behaviours and should continue to be used, but with these flaws and biases acknowledged in future research.

Furthermore, all the self-report measures used in this research were state-based measures of the construct specific to adherence behaviours (e.g., intention, habit, cues, behaviour), apart from the measures of self-regulatory capacity which were trait-based. The use of general state-based measures of self-regulation, self-

control and planning, such as the Self-Regulation Questionnaire (Brown et al., 1999) or the Brief Self-Control Scale (Tangney et al., 2004) is common in research in health and social behaviours (Evans et al., 2017; Mullan et al., 2021). These measures were used as they are not only commonly used but have also undergone reliability and validity testing. Research that continues to explore the role of self-regulatory capacity in adherence should consider using specific state-based measures of this construct, like those used when applying the health action process approach (Reyes Fernández et al., 2016), for example, "thinking of the next week, I have made a concrete and detailed plan...regarding my medication taking".

Within the literature, there are very few measures of environmental cues and thus the Cues to Action Scale (Booker & Mullan, 2013) was chosen as it is a commonly used measure (e.g. (Moran & Mullan, 2020; Murray & Mullan, 2019) and incorporates five different types of cues. Despite it being commonly used, the measure has yet to undergo psychometric testing and thus the validity of the measure as a measure of cues is not well known. However, some research in the field is currently underway to determine and validate behaviour specific Cues to Action Scales, such as to alcohol consumption (Girdlestone et al., 2020) as well as exploring the reliability and validity of the current measure (McAlpine et al., 2021). Future research exploring cues in adherence should consider creating and validating a measure of cues specific to medication adherence. Researchers should consider removing the questions that relate to 'how often' the cue is experienced, as the scoring of the measure assumes that the more the cue is identified/present, the greater the engagement in behaviour. However, this is unlikely to be the case

for behaviours such as medication adherence where most often than not, there are a few specific cues that prompt the behaviour (e.g., time of day, daily activity), and experiencing too many cues is counterproductive. Similarly, researchers also need to consider the complexity of the medication regimen when using this measure, such that more cues may be experienced by those that are required to take more medications, compared to those that take only one or two, but the number of cues experienced may not be conducive with better adherence.

All the concerns with the measures used in this thesis build on the current research by further highlighting the previously identified issues. However, researchers must be also critically thinking about the measures that are used to measure medication adherence behaviour, as some of the most commonly used measures of adherence are not actually measuring behaviour but rather attitudes/beliefs towards adherence.

Throughout this thesis, different measures of adherence were shown to result in different relationships and findings (Chapters 2, 3 and 6). Use of a variety of commonly used and freely available self-report measures of adherence, including the Medication Adherence Rating Scale (Thompson et al., 2000), Medication Adherence Report Scale (Horne & Weinman, 1999; Molloy et al., 2012) and Timeline Follow-Back (Liddelow, Mullan, & Novoradovskaya, 2020; Sobell & Sobell, 1992), show there are differences between the measures, but as yet there is no gold standard self-report measure of medication adherence.

The Medication Adherence Rating Scale (Thompson et al., 2000) was used in Chapter 3 and it was identified that this measure contained several items that

assess attitudes rather than actual behaviour (e.g. “my thoughts are clearer on medication” and “it is unnatural for my mind and body to be controlled by medication”). The inclusion of such questions reduces the validity and reliability of this measure as a measure of behaviour. The Medication Adherence Report Scale (Horne & Weinman, 1999; Molloy et al., 2012), used in Chapters 5 and 6, could be considered a better measure of medication adherence as it includes five items that specifically refer to medication-taking behaviour (e.g. in the last two weeks did you...forget to take your medication?). However, despite these strengths, it is not known how well the measure prompts accurate recall of adherence as it does not require the reporting of specific daily routines or behaviours. The Timeline Follow-Back (Liddelow, Mullan, & Novoradovskaya, 2020; Sobell & Sobell, 1992) used in Chapter 3 and 6, however, is presented in a calendar-like format that requires the individual to think specifically about their previous week to ensure a more accurate recall of adherence. Despite this measure being a good measure of behaviour, it is not without its limitations. As identified in Chapter 5, some participants may be unwilling to complete it due to the large amount of work it is perceived to involve and the length of instructions. Thus, although it is a good measure of behaviour, it is important that researchers who continue to use this measure think about making it more user-friendly, such as providing shorter and clearer instructions and providing an example of a completed Timeline Follow-Back. With that being said, a more user-friendly Timeline Follow-Back can be considered the better measure of adherence as it promotes a more accurate recall of behaviour and should continue to be used in research. However, more research

into how best to assess medication adherence through self-report is clearly warranted. Despite issues with the measures, self-report measures of adherence should still be used in research as they allow for the measurement of behaviour in geographically hard to reach populations, as well as allow for internet-based research to occur. However, their limitations need to be considered and acknowledged by researchers using them.

Summary of Research Findings – Aim Two

The second aim of this research project was to see if improvements could be made to medication adherence by designing and implementing a simple intervention based on the findings of the previous chapters. Chapters 5 and 6 addressed this aim by first identifying additional important malleable predictors of adherence and an appropriate population to target and then implementing a simple intervention. In Chapter 5, findings showed moderate-to-strong positive associations between knowledge, health literacy and adherence to the pill. Adherence to the pill in this sample was also less than perfect, suggesting sufficient variability in adherence and a suitable sample to target an intervention towards. In Chapter 6 the intervention was implemented through the use of behaviour change techniques (BCT) from Michie et al. (2013), to target behaviour change through habit. Specifically, cues were used as a BCT because previous chapters had identified their importance in adherence, and knowledge was also used as the previous chapter identified its role in adherence to the pill. There were

no significant intervention effects on pill adherence and such, the findings did not support the role of either cues or knowledge in improving adherence to the pill.

Intervention Research Findings and Implications

Habit strength significantly increased over time across all conditions, as well as the presence and influence of physical cues. Despite seeing changes in habit strength, this did not lead to changes in behaviour, which is inconsistent with previous research using a similar intervention design (Novoradovskaya et al., 2020). This is important as it highlights limitations of the current intervention, but also provides directions for the future of intervention development and implementation in this behaviour.

One possibility for this lack of change in adherence behaviour is that participants who were randomised to a group with the cue implementation BCT were asked to select a cue to match with their pill taking. It is likely that some participants already used cues to assist with taking their medication, but instead may have chosen a new cue and therefore they were now experiencing too many cues, which negatively influenced their adherence. This is similar to what was identified in the predictive study in Chapter 2.

Secondly, the intervention period of six weeks was based on previous research that showed simple behaviours only need 33 days to become habitual (Mullan et al., 2017). However, it seems as though this is not the case with adherence, possibly because the behaviour of taking the pill is not novel whereas the behaviour in the study by Mullan et al. (2017) was novel and had not been previously performed by participants. Coinciding with this, a recent study

published after the implementation of the intervention suggests that novel simple behaviours actually take 59 days to reach peak automaticity (Keller et al., 2021). Therefore, it may be that breaking habits (e.g. a behaviour that has been performed previously and is not novel, like taking the pill) are harder than just forming a new habit, and therefore adherence behaviour requires longer periods to reach peak habit strength when being targeted in interventions.

Thirdly, the intervention was conducted online over six weeks; however, there was limited interaction between the researchers and the participants. Perhaps contact with researchers is needed as has been demonstrated in a previous review of computer-delivered interventions (Black et al., 2016). Previous intervention research has suggested that monitoring is important (Mullan et al., 2014) and therefore if participants engaged in self-monitoring throughout the intervention period, there may have been a change in behaviour. Finally, the sample size of the intervention was small with only 81 participants completing both baseline and follow-up. As a result, the intervention needs to be conducted with a larger sample to ensure not only greater variability in adherence to the pill is captured, but also to better understand the intervention effects across a larger range of individuals.

Going forward, the lack of intervention effect on behaviour suggests amendments to the current intervention are required to be implemented to experience not only changes in habit but also adherence. Based on the suggestions above, a larger sample could be recruited, and the intervention period extended to at least 8 weeks. Researchers should also ensure that participants are explicitly told to select a cue they already use and if they do not have one already, to select an

appropriate cue. To ensure monitoring of the behaviour, participants should be sent an email with the group they were randomised to and the instructions they should follow for the next few weeks. This will assist with the possibility of participants forgetting what group they were randomised to, but also allows them the opportunity to check back and remind themselves. It may also be beneficial to ask participants to complete a measure of adherence and habit strength weekly, using a mobile application, to monitor the formation of the habit, as has been done previously (Keller et al., 2021; Lally et al., 2010; Novoradovskaya et al., 2020).

Limitations and Future Directions

The majority of the limitations of this body of research are presented in each of the individual chapters and identified the limitations associated with self-report measures, correlational data, and crowdsourcing platforms. The use of cross-sectional and correlational research designs within this thesis means temporal ordering between many of the factors and adherence are unable to be determined. Before more experimental research is conducted using Temporal Self-Regulation Theory as a theoretical basis, a longitudinal study which measures adherence to medication in the long term (e.g., 8 weeks) may be worthwhile to explore which constructs of the theory are consistent over time in natural settings. If a construct is not able to predict a behaviour over time, it may not be important in that behaviour and thus should not be the focus of interventions aimed at improving it.

If theoretical constructs are identified as being important in longitudinal designs, these constructs then provide information for what should then be experimentally investigated through interventions aimed at improving behaviour (Glanz et al., 2015; Glanz & Bishop, 2010). This would provide additional evidence for or against the theory and its efficacy as a theory of behaviour change. If possible, both of these future studies should be conducted in-person rather than online, to ensure both objective and subjective measures of adherence can be used, as the research in this thesis was limited to only subjective measures of adherence.

Similarly, during the theory testing phase of this thesis (Chapters 2, 3 and 4), the theory was applied to general medication adherence. However, this thesis identified differences in the factors important to adherence in simple and complex regimens. Therefore, future research should explore the applicability of the theory in similar prospective designs to both a simple medication regimen and a more complex medication regimen to corroborate with the qualitative findings of this thesis. Similarly, future research should consider applying the theory to different experiences of medication adherence, which I was unable to do as part of this thesis. For example, cystic fibrosis is a lifelong condition that begins in early childhood and adherence to this complex long-term regimen of medications is likely to be predicted by different factors compared to mild asthma that is identified in later adulthood. The individual complexities of medication adherence, need to be further considered when conducting research in this area. This body of research also did not account for nor control for baseline knowledge and skills related to medication adherence (health literacy and knowledge) and evidence was

provided for their importance in adherence. Future research should therefore ensure these factors are considered when conducting both correlational and experimental research and consider extending current behaviour change models to include the role of these factors.

Due to ease of recruitment and time limitations, the populations in each of the research studies in this thesis were all from high-income countries (Australia and the US), tended to be younger and taking long-term prescription medication. This may also mean that generally, these individuals are more highly educated and health literate compared to other populations. Therefore, it is important to investigate whether Temporal Self-Regulation Theory and its constructs operate similarly in different populations, such as those from low-income countries, in older adults and in prophylactic or acute medications where adherence has been shown to be poorer (e.g. Craig & Wright, 2012; Eells et al., 2016). It is also important to consider which populations need adherence interventions the most and ensure research and interventions attempt to target them also.

Conclusion to the Thesis

In the current thesis, I aimed to build on previous research by exploring the malleable predictors of medication adherence through the application of Temporal Self-Regulation Theory. Based on these findings, the second aim was to create and implement a simple intervention to explore whether changes could be made to adherence. The studies in this research present the first studies to apply Temporal Self-Regulation Theory to medication adherence. Overall, the findings found

partial support for the applicability of the theory in adherence to medications, but also raises questions regarding the reliability and validity of the theory as a theory of behaviour change, providing many avenues for future research. An intervention targeting cues was unsuccessful in changing behaviour, but was successful in increasing habit, suggesting that changes in theoretical constructs do not always lead to changes in behaviour. The measurement of adherence became an aim after the first study identified different findings as a result of the type of self-report measure used, whether it was attitudes/beliefs based or behaviour based. The continued use of the Timeline Follow-Back as a measure of adherence is recommended. Future research needs to continue investigating the applicability of Temporal Self-Regulation Theory and its predicted interactions, but to more specific medication regimens and populations, and if feasible, using both objective and subjective measures of medication adherence to ensure a greater understanding of the theory in this behaviour.

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Appendices

Appendix A

Ethics Approval Letter for Chapters 3, 4, and 5



Office of Research and Development

GPO Box U1987
Perth Western Australia 6845

Telephone +61 8 9266 7863
Facsimile +61 8 9266 3793
Web research.curtin.edu.au

12-Apr-2017

Name: Barbara Mullan
Department/School: School of Psychology and Speech Pathology
Email: Barbara.Mullan@curtin.edu.au

Dear Barbara Mullan

RE: Amendment approval
Approval number: HRE2017-0173

Thank you for submitting an amendment request to the Human Research Ethics Office for the project **Predicting habitual behavior**.

Your amendment request has been reviewed and the review outcome is: **Approved**

The amendment approval number is HRE2017-0173-03 approved on 12-Apr-2017.

The following amendments were approved:

Addition of Co-investigator: Penelope Hasking.

Addition of 2 Student investigators: Caitlin Liddelow and Kristen Montague.

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

Appendix B

PRISMA 2009 Checklist – Chapter 2



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	42
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	43-44
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	47-48
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	49-50
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	51
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	52
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	51-52
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	53

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	53-54
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	54
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	54
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	64
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	55
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	54-56

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	64
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	56-57
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	57-58/60
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	58-59
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	89-92
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	65-80
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	61-65

Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	64
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	62-63
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	93-97
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	98-100
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	100-101
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	N/A

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

Appendix C

Participant Information Sheet – Chapter 3



Participant Information Sheet **Understanding Medication Adherence**

Dear Participant,

My name is Caitlin Liddelow and I am a PhD student in the School of Psychology at Curtin University in Perth, Western Australia. I am being supervised by Associate Professor Barbara Mullan and Dr Mark Boyes from the School of Psychology. Together, we are exploring some of the psychological influences of adherence to prescription medication. We would like to invite you to participate in this research study that aims to understand the influence that psychological factors have on adherence to prescription medication. The overall aim of the study is to understand how particular factors influence adherence and it is hoped that this information can one day be included in interventions to improve adherence to medication.

What does it involve and how can you take part?

To take part in this study you must be a mature minor (over the age of 16 years) and be able to understand the English language.

This study includes two questionnaires that you will complete one week apart.

- If you agree to take part in the study, by checking the box at the start of the questionnaire, you will be guided through questionnaire one.
- One week following your completion of questionnaire one you will be sent an invitation to complete questionnaire two.

How much of your time will participation involve?

- Questionnaire one will take approximately 10-15 minutes to complete, depending on your answers
- Questionnaire two will take approximately 5 minutes to complete

Will your participation in the project remain confidential?

If you agree to take part, you will be required to enter both a unique code and an email address, so you can receive part two of the questionnaire. Your unique code will be used to anonymously match part one and part two of the questionnaire. Once both questionnaires are complete and matched up, your details will be removed from the data including your unique code and email. You can be confident that if you take part in the study you will remain anonymous and the information you provide will not be disclosed to other parties, only the research team will see your individual answers. Electronic data will be password-protected on Qualtrics and the Curtin University research drive. The information collected will be kept for 7 years after the research has ended. It will then be

destroyed. The results of this study may be presented at conferences or published in professional journals. We will not use any identifying information in any published materials.

What are the advantages of taking part?

The information collected will be used to help us understand the ways that psychological factors can influence medication adherence. As per Mechanical Turk, you will receive monetary reimbursement for your participation in the study.

What are the disadvantages of taking part?

We do not believe there are any risks to you from participating in the research. However, sometimes the questions can trigger emotions. If you do experience any distress from any of the questions many online resources are available including:

- Suicide Prevention Lifeline: <https://suicidepreventionlifeline.org/>
- National Alliance on Mental Illness (NAMI) <https://www.nami.org/#>
- I'm Alive <https://www.imalive.org/>

Do you have to take part in the study?

No, participation in this study is entirely voluntary. If you do not wish to participate you are free to discontinue with the study at any time if you change your mind, without any repercussions.

Who can I contact if I have any questions or concerns?

If you have any questions, please do not hesitate to contact us:

Caitlin Liddelow at caitlin.liddelow@postgrad.curtin.edu.au or

Associate Professor Barbara Mullan at barbara.mullan@curtin.edu.au. Phone: +61 08 9266 2468

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2017-0173). Should you wish to discuss the study with someone not directly involved, in particular that of 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

Appendix D

Qualtrics Survey – Part One – Chapter 3

Consent

Q1 Do you consent to participate in this study?

- Yes
- No

Q2 Do you take prescription medicine? For example: cholesterol-lowering medication, anti-depressants.

- Yes
- No

Demographics

Q3 Please enter your Mechanical Turk or Turk Prime worker ID

Q4 What is your age in years? Please type in numbers

Q5 How do you identify?

- Male
- Female
- Other gender

Q6 What is your current living situation?

- Living alone
- Living with parents/family
- Living with friends/house mates/flat mates
- Living with partner
- Other

Q7 What is your singular current annual income?

- Under \$18,000
- \$18,000 - \$37,000
- \$37,000 - \$87,000
- \$87,000 - \$110,000
- \$110,000 - \$180,000
- Over \$180,000

Q8 What is your country of residence?

- United States of America
- Australia
- Canada
- Other

Q9 How would you predominantly describe yourself?

- African American
- Hispanic or Latino
- American Indian or Alaska Native
- Caucasian
- Asian
- Native Hawaiian or Other Pacific Islander
- European
- Middle Eastern
- Other _____

Q10 What is your current health insurance coverage status? Please select all that apply

- Insurance through a current employer or union
- Insurance purchased directly from an insurance company (private insurance)
- Medicare (aged 65 and over)
- Medicaid, Medical Assistance or any government-assistance
- Public Health Insurance (e.g. OHIP, MSP, AHCIP, RMAQ, Saskatchewan Health Card or Manitoba Health)
- TRICARE or other military health care
- VA health care

- Indian Health Service
- Not insured

Q11 How many different medicines do you take? Please write as a number

Q12 What is the health condition that you take each of these medicines for? Please specify

Medication Regimen Complexity Index

Q1. In what form/route do you take your medicine/s? Please select all that apply

- Tablet - Oral (by mouth)
- Spray - Topical (on skin)
- Gel - Topical (on skin)
- Spray - Nasal (in the nose)
- Drop - Oral (by mouth)
- Drop - Ophthalmic (in eyes)
- Accuhaler (Inhalation)
- Ampoule pen - Subcutaneous (injection/under the skin)
- Ampoule - Subcutaneous (injection/under the skin)
- Liquid - Intravenous (into veins)
- Implant - Subcutaneous (under the skin)

Q2. Please select your dosing frequency (how often you take your medicine) for your _____,

from the options below. *Note: This scale was provided for each type of medicine selected in Q1*

- Once daily as needed
- Once daily
- Twice daily
- Twice daily as needed
- Three times daily
- Three times daily as needed

- Four times daily
- Four times daily as needed
- Every 8 hours
- Every 8 hours as needed
- Every 6 hours
- Every 6 hours as needed
- Every 4 hours
- Every 4 hours as needed
- Every 2 hours
- Every 2 hours as needed
- On alternate days or less frequently

Q3. Are any of the special instructions below part of your medicine regimen? Please select all that apply. If you have no special instructions, please continue to the next question

- Break or crush tablet
- Dissolve tablet/powder
- Multiple units at one time (e.g., 2 tablets, 2 puffs)
- Variable dose (e.g., 1-2 tablets, 2-3 puffs)
- Take/use at specified times (e.g., morning, night, 8am, 9pm)
- Relation with food (e.g., before food, with food, after food)
- Take with specific fluid
- Take/use as directed
- Tapering/increasing dose
- Alternating dose (e.g., one in the morning and two at night, one/two on alternating days)

Cues to Action Scale

Physical Cues

Q1. Are there any physical things in the environment which trigger you to take your medicine? *Note: If answered 'no' was taken to next type of cue*

- Yes
- No

Q2. How often do you see these cues?

	Never	A few times a year	Monthly	A few times a month	Every week	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q3. How much is seeing these cues likely to make you take your medicine?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer

Sensory Cues

Q4. Are there any sensory things in the environment which trigger you to take your medication? (e.g., a certain smell)

- Yes
- No

Q5. How often do you experience these cues?

	Never	A few times a year	Monthly	A few times a month	Every week	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q6. How much is experiencing these cues likely to make you take your medicine?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer

Social Cues

Q7. Are there any social situations which trigger you to take your medicine?

- Yes

- No

Q8. How often are you in these situations?

	Never	A few times a year	Monthly	A few times a month	Every week	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>							

Q9. How much is being in these situations likely to make you take your medicine?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer



Internal Cues

Q10. Are there any internal drives which trigger you to take your medicine? (e.g., feeling sleepy, hungry, thirsty)

- Yes
- No

Q11. How often do you feel these cues?

	Never	A few times a year	Monthly	A few times a month	Weekly	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>							

Q12. How much is feeling these cues likely to make you take your medicine?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer



Past Behaviour

Q1. Ensuring that I take my medicine correctly is something...

	Strongly Disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
I do frequently	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Brief Self-Control Scale

Q1. Using the scale below, please indicate how much each of the following statements reflects how you typically are:

	Not at all like me	A little like me	Somewhat like me	Mostly like me	Very much like me
I am good at resisting temptation	<input type="radio"/>				
I have a hard time breaking bad habits	<input type="radio"/>				
I am lazy	<input type="radio"/>				
I say inappropriate things	<input type="radio"/>				
I do certain things that are bad for me, if they are fun	<input type="radio"/>				
I refuse things that are bad for me	<input type="radio"/>				
I wish I had more self- discipline	<input type="radio"/>				
People would say that I have iron self-discipline	<input type="radio"/>				
Pleasure and fun sometimes keeps me from getting work done	<input type="radio"/>				
I have trouble concentrating	<input type="radio"/>				
I am able to work effectively toward long- term goals	<input type="radio"/>				

Sometimes I can't stop myself from doing something, even if I know it is wrong

I often act before thinking through all the alternatives

“Planning Subscale” from Self-Regulation Questionnaire

Q1. Please answer the following questions by selecting the response that best describes how you are.

There are no right or wrong answers. Work quickly and don't think too long about your answers

	Strongly disagree	Disagree	Uncertain/Unsure	Agree	Strongly agree
I have trouble making up my mind about things	<input type="radio"/>				
I put off making decisions	<input type="radio"/>				
When it comes to deciding about a change, I feel overwhelmed by the choices	<input type="radio"/>				
I can come up with lots of ways to change, but it's hard for me to decide which one to use	<input type="radio"/>				
I have a hard time setting goals for myself	<input type="radio"/>				
I have trouble making plans to help me reach my goals	<input type="radio"/>				
Once I have a goal, I can usually plan how to reach it	<input type="radio"/>				
I usually think before I act	<input type="radio"/>				
Before making a decision, I consider what is likely to happen if I do one thing or another	<input type="radio"/>				

Intention

Q1. Please answer the following statements truthfully using the scale below

Strongly disagree	Disagree	Somewhat disagree	Neither agree	Somewhat agree	Agree	Strongly agree
-------------------	----------	-------------------	---------------	----------------	-------	----------------

				nor			
				disagree			
I intend to ensure that I take my medicine correctly, as prescribed, over the next week	<input type="radio"/>						
I will try to ensure that I take my medicine correctly, as prescribed, over the next week	<input type="radio"/>						

Side Effects

Q1. Do you experience any side-effects from taking your medicine?

- Yes
- No

Q2. Please specify what type of side effects you experience

- Sleeping troubles
- Constipation/diarrhoea/bowel troubles
- Skin rashes
- Dizziness
- Drowsiness
- Dry mouth
- Headache
- Nausea
- Suicidal thoughts
- Abnormal heart rhythms
- Internal bleeding
- Fatigue
- Muscle/joint pain or stiffness
- Reduced sex drive and/or sexual troubles
- Loss of appetite
- Moodiness

Q3. Do you believe this influences your overall medicine adherence?

- Definitely yes
- Probably yes
- Might or might not
- Probably not
- Definitely not

Appendix E

Qualtrics Survey – Part Two – Chapter 3

Measures (Part Two)

Medication Adherence Rating Scale

Q1. Please answer the following questions/statements truthfully regarding your medicine taking behaviour over the previous week

	Yes	No
Do you ever forget to take your medication?	<input type="radio"/>	<input type="radio"/>
Are you careless at times about taking your medication?	<input type="radio"/>	<input type="radio"/>
When you feel better, do you sometimes stop taking your medication?	<input type="radio"/>	<input type="radio"/>
Sometimes if you feel worse when you take the medication, do you stop taking it?	<input type="radio"/>	<input type="radio"/>
I take my medication only when I am sick	<input type="radio"/>	<input type="radio"/>
It is unnatural for my mind and body to be controlled by medication	<input type="radio"/>	<input type="radio"/>
My thoughts are clearer on medication	<input type="radio"/>	<input type="radio"/>
By staying on medication, I can prevent getting sick	<input type="radio"/>	<input type="radio"/>
I feel weird, like a "zombie", on medication	<input type="radio"/>	<input type="radio"/>
Medication makes me feel tired and sluggish	<input type="radio"/>	<input type="radio"/>

Timeline Follow-Back

Q3 Please provide accurate information. This will help you reconstruct your LAST week, not the average week. It is important for you to try and remember what was not usual during the previous week (you felt sick, attended a party, travelled, been at work longer hours etc.) and how this impacted correctly taking your medication.

Using the below calendar, please reconstruct the use of your prescription medicine in the past week and what events impacted this, if any. The following are instructions and tips for completing the record:

1. It is important that for each of the seven days, there is a number in each box.
2. In the “Special Events” please indicate if there were any holidays, celebration or any other events that do not occur every week, e.g., birthday, exam, party etc.
3. On the days that you did not take your medicine, mark those days with a ‘0’.

4. On the days that you did take your medicine, write in the total number of times you took your medication on those days. The important thing is to make sure that something is filled in for each of the seven days.
5. On the days that you did take your medicine, write the number of times you took your medication correctly, as prescribed.
6. Please be as accurate as possible.

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Day/date (e.g., Monday 7/5/18)							
Did you have any special events this day? Please specify							
Number of times taken your medicine today							
Did you take each medicine as prescribed by your doctor? (e.g., with food, at the right time)							

Appendix F

Extended Results - Chapter 3

Principal component analysis was conducted on the 10 items. It was assumed that the measure would be unidimensional based on the initial psychometric paper (Thompson et al., 2000), therefore one factor was forced. The KMO value was .798 and Bartlett's Test was also significant ($p < .001$), suggesting the items were suitable for factor analysis. Inspection of the scree plot supported our assumptions of a unidimensional measure and identified one factor which accounted for 31.29% of variance (see Table 1 for the component matrix). A decision was made to remove items that were not loading onto the one factor. Factors with a value over 0.5 were retained (MacCallum et al., 1999) and principal component analysis was run for a second time, this time only using seven of the 10 items. The removal of items one, seven and eight increased the variance accounted for to 42.54% (see Table 2 for the component matrix).

Table 1.

Factor structure for 10-item Medication Adherence Rating Scale

Item	Factor 1
Sometimes if you feel worse when you take the medication, do you stop taking it?	.721
When you feel better, do you sometimes stop taking your medication?	.720
I take my medication only when I am sick	.634
Medication makes me feel tired and sluggish	.631
Are you careless at times about taking your medication?	.615
I feel weird, like a "zombie", on medication	.596
It is unnatural for my mind and body to be controlled by medication	.585
Do you ever forget to take your medication?	.371
My thoughts are clearer on medication	
By staying on medication, I can prevent getting sick	

Note: Factor loading <.3 have been suppressed

Table 2.

Oblimin rotated factor structure for the seven item Medication Adherence Rating Scale

Item	Factor 1
When you feel better, do you sometimes stop taking your medication?	.735
Sometimes if you feel worse when you take the medication, do you stop taking it?	.722
I take my medication only when I am sick	.656
Medication makes me feel tired and sluggish	.654
I feel weird, like a "zombie", on medication	.626
It is unnatural for my mind and body to be controlled by medication	.577
Are you careless at times about taking your medication?	.576

Table 3.

T-test results showing completers vs. non-completers

	Completers		Non-Completers		<i>t</i>	<i>d</i>	Sig. (2-tailed)
	Mean	SD	Mean	SD			
Age	37.83	11.61	35.64	12.30	0.15	300	.702
SES	3.42	1.27	3.60	1.19	1.24	312	.215
Regimen	4.23	2.60	7.25	9.13	3.57	133.66	.001**
Side-effects	0.94	1.60	1.18	2.04	1.15	312	.252
Intention	6.26	0.95	5.71	1.16	-4.49	218.83	.000**
Past behaviour	5.79	1.24	5.41	1.37	-2.50	241.41	.013*
Habit	4.92	1.49	5.04	1.30	0.71	312	.480
Cues	20.32	30.16	38.98	44.25	4.44	194.73	.000**
Self-Regulation	76.28	15.39	67.66	12.18	-5.52	298.98	.000**

Note. ** $p < .001$, * $p < .05$

Table 4.

Chi-squared of completers vs. non-completers by gender

	Completers	Non-Completers	χ^2	<i>d</i>	Sig. (2-tailed)
Gender			0.15	1	.702
Male	99	60			
Female	89	59			

Note. ** $p < .001$, * $p < .05$

Table 5.

Regression output for predicting medication adherence using the revised seven-item Medication Adherence Rating Scale

Variable	<i>B</i> [95% CI]	β	<i>sr</i> ²	<i>p</i> -value	<i>R</i> ²	ΔR^2	<i>F</i>	ΔF (<i>df</i> 1, <i>df</i> 2)
Step 1				.018*	.055	.055	3.431	3.431 (3, 176)
Age	.509 [.191, .827]	.235	.05	.002**				
Gender	-.116 [-.769, .537]	-.028	.00	.726				
SES	.052 [-.266, .369]	.025	.00	.749				
Step 2				.000**	.193	.138	8.333	14.875 (2, 174)
Age	.471 [.175, .767]	.218	.05	.002**				
Gender	.100 [-.515, .714]	.024	.00	.749				
SES	-.022 [-.320, .276]	-.011	.00	.884				
Regimen	-.914 [-1.602, -.226]	-.179	.03	.009**				
Side Effects	-.700 [-.993, -.407]	-.331	.10	.000**				
Step 3				.000**	.452	.293	14.430	15.935 (6, 168)
Age	.162 [-.094, .417]	.075	.00	.213				
Gender	-.538 [-1.064, -.011]	-.128	.01	.046*				
SES	-.149 [-.396, .098]	-.072	.00	.235				
Regimen	-.775 [-1.363, -.187]	-.152	.02	.010**				
Side Effects	-.319 [-.578, -.060]	-.151	.02	.016*				
Intention	-.096 [-.428, .235]	-.040	.00	.567				
Past Behaviour	.633 [.325, .941]	.287	.05	.000**				
Habit	.042 [-.208, .293]	.021	.00	.739				
Cues to Action	-.933 [-1.263, -.603]	-.363	.10	.000**				
Self-Control	.474 [.122, .825]	.224	.02	.009**				
Planning	.119 [-.222, .460]	.057	.00	.491				
Step 4				.000**	.525	.479	11.282	2.725 (5, 163)
Age	.175 [-.077, .427]	.081	.01	.173				

Gender	-.404 [-.928, .120]	-.096	.01	.130
SES	-.148 [-.393, .098]	-.071	.00	.236
Regimen	-.918 [-1.499, -.338]	-.180	.02	.002**
Side Effects	-.273 [-.531, -.015]	-.129	.01	.038*
Intention	-.197 [-.594, .200]	-.081	.00	.329
Past Behaviour	.615 [.309, .921]	.279	.05	.000**
Habit	.219 [-.060, .498]	.111	.01	.123
Cues to Action	-1.014 [-1.344, -.683]	-.394	.11	.000**
Self-Control	.424 [.016, .832]	.201	.01	.042*
Planning	.052 [-.309, .414]	.025	.00	.775
IntentionXPB	.062 [-.207, .332]	.033	.00	.647
IntentionXHabit	-.487 [-.811, -.163]	-.231	.03	.003**

Note: SES = socioeconomic status, PB = past behaviour, SC = self-control. Significant steps and predictors are shown in bold. * $p < .05$ ** $p < .01$

Table 6.

Regression output for predicting medication adherence using the adapted Timeline Follow-Back

Variable	<i>B</i> [95% CI]	β	<i>sr</i> ²	<i>p</i> -value	<i>R</i> ²	ΔR^2	<i>F</i>	ΔF (<i>df</i> 1, <i>df</i> 2)
Step 1				.172	.028	.028	1.684	1.684 (3, 176)
Age	.479 [-.095, 1.052]	.125	.01	.101				
Gender	-.853 [-2.031, .325]	-.114	.01	.155				
SES	.134 [-.439, .707]	.036	.00	.645				
Step 2				.208	.040	.012	1.452	1.101 (2, 174)
Age	.461 [-.113, 1.035]	.120	.01	.115				
Gender	-.717 [-1.908, .475]	-.096	.01	.237				
SES	.075 [-.503, .654]	.020	.00	.798				
Regimen	.008 [-1.326, 1.341]	.001	.00	.991				
Side Effects	-.428 [-.996, .141]	-.114	.01	.140				
Step 3				.001**	.164	.124	2.992	4.143 (6, 168)
Age	.062 [-.517, .640]	.016	.00	.834				
Gender	-1.562 [-2.756, -.368]	-.209	.03	.012*				
SES	-.050 [-.609, .509]	.014	.00	.861				
Regimen	.418 [-.915, 1.751]	.046	.00	.537				
Side Effects	.087 [-.500, .675]	.023	.00	.769				
Intention	.561 [-.191, 1.312]	.130	.01	.143				
Past Behaviour	-.161 [-.859, .537]	-.041	.00	.649				
Habit	.120 [-.447, .687]	.034	.00	.677				
Cues to Action	-.971 [-1.718, -.223]	-.212	.03	.011*				
Self-Control	1.098 [.302, 1.894]	.293	.04	.007**				
Planning	-.389 [-1.162, .384]	-.104	.00	.322				
Step 4				.001**	.206	.128	2.641	1.727 (5, 163)
Age	.134 [-.446, .714]	.035	.00	.650				

Gender	-1.687 [-2.892, -.481]	-.225	.04	.006**
SES	-.070 [-.634, .494]	-.019	.00	.807
Regimen	.534 [-.802, 1.869]	.059	.00	.431
Side Effects	.137 [-.457, .731]	.036	.00	.650
Intention	1.214 [.301, 2.127]	.282	.03	.008**
Past Behaviour	.001 [-.702, .705]	.000	.00	.997
Habit	-.096 [-.738, .546]	-.027	.00	.768
Cues to Action	-.825 [-1.584, -.066]	-.180	.02	.033*
Self-Control	.996 [.057, 1.935]	.265	.02	.038*
Planning	-.555 [-1.386, .275]	-.149	.01	.189
IntentionXPB	.427 [-.192, 1.046]	.127	.01	.175
IntentionXHabit	.332 [-.413, 1.078]	.088	.00	.380
IntentionXCues	.682 [-.232, 1.596]	.119	.01	.143
IntentionXSC	.241 [-.850, 1.332]	.050	.00	.664
IntentionXPlanning	-.016 [-.988, .957]	-.003	.00	.975

Note. SES = socioeconomic status, PB = past behaviour, SC = self-control. Significant steps and predictors are shown in bold.

* $p < .05$ ** $p < .01$

Appendix G

Permission to Include Copyrighted Article in Thesis – Chapter 3

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Understanding the predictors of medication adherence: applying temporal self-regulation theory

Author: Caitlin Liddelow, , Barbara Mullan, et al

Publication: Psychology and Health

Publisher: Taylor & Francis

Date: Jul 8, 2020

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Appendix H

Participant Information Sheet – Chapter 4



Participant Information Sheet- Medication Adherence Interview

Project Title: How medication regimes, side effects and motivations influence medication adherence behaviours: A qualitative study

Project Summary: You are invited to participate in a research study being conducted by PhD student Caitlin Liddelow, Associate Professor Barbara Mullan and Dr Mark Boyes from the School of Psychology at Curtin University. This research will explore the potential role and influence that medication regimens, side-effects, motivations and barriers influence medication adherence. It seeks to understand ways in which medication adherence is influenced by these factors and also ways in which it can improved.

How is the study being paid for?

The project is funded by Curtin University Higher Degree by Research program and supported by an Australian Government Research Training Program Scholarship.

Why am I being asked to take part and what will I be asked to do?

We are inviting those who take regular prescription medication/s for an ongoing health concern to be interviewed regarding their adherence behaviours. Taking part will involve answering some short demographic questions in an online questionnaire prior to the interview. This will take approximately 2 minutes. You will then be participating in one interview which will be in person, or via telephone if necessary. You will be asked questions about your medication usage and regimen, motivations for adhering or not adhering, your experience of side effects and other barriers and facilitators of your medication adherence. The interview will take between 45-60 minutes.

If you agree, the interview will be audio-recorded. Notes will also be taken by the interviewer throughout the interview. A summary of the interview will be sent to you within a few weeks after the interview once it has been transcribed into text. You are invited to make changes and provide feedback so that it is an accurate reflection of your thoughts and experiences. The interview will take place at Curtin University, or a location that is convenient for you.

Are there any benefits to being in this research project?

There may be no direct benefit to you from participating in this research. However sometimes people appreciate the opportunity to discuss their experiences. We hope the results of this research will allow us to add to the current knowledge surrounding what influences medication adherence behaviours in people who take all kinds of medication.

We hope it will guide a future intervention aimed at improving adherence rates by targeting particular predictors of adherence.

Are there any risks or side-effects to taking part?

Apart from giving up your time, we do not expect there to be any major risks associated with taking part in this study. Some participants may feel uncomfortable or a degree of distress from answering questions related to their current medication usage. If this does occur, a sheet with contacts to the Curtin University counselling service, Lifeline and other hotlines and websites will be provided.

How will the information be used?

The information collected in your interview will be combined with information collected from other interviews and used to produce research findings. These research findings will be written into a thesis and published in academic articles. Quotes from the interview may be used when the findings are published but they will be presented in a way that does not identify you.

Who will have access to my information and how will my information be stored?

Prior to the interview you will provide some identifying information (e.g. name, email address) to allow the researcher's to contact you to arrange a time for the interview to occur. After the interview and prior to analysis, the data will be identifiable so that a summary of your interview can be sent to you for feedback. After approval from yourself, all identifying information will be removed and the interview will be added to the other non-identifiable data. During the study, data will be stored on a password protected laptop at Curtin University that only the researchers can access. After the study is completed, electronic data will be stored in a secure file on a password locked computer on the University's Research drive. The data will be kept securely for seven years and then it will be destroyed. The following people will have access to the information collected 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.

Will you tell me the results of the research?

You will not receive the final results of the study, however you will receive a summary of your individual interview and data to provide feedback on the interpretation of your interview. If you wish to obtain the final results of the study you can contact the researchers in early 2020 to receive a link to access the published article in a peer-reviewed journal. The results may also be presented in professional presentations or at conferences.

Do I have to take part in the research project?

Taking part in a research project is voluntary. It is your choice to take part or not. You do not have to agree if you do not want to. 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, staff or colleagues

Who can take part?

- You are aged 16 years and older

- Take regular prescription medication/s for an ongoing health concern
- Understand and speak the English language fluently

Participation is entirely voluntary and you are not obliged to be involved. If you choose to participate, you can withdraw at any time before the analysis of data, while the data is still identifiable. After this point, all identifying information will be removed and it will not be possible to identify who the interview data is from. If you would like to withdraw, you do not have to give a reason and will not experience any repercussions from the researchers or Curtin University.

If you do decide to withdraw, simply contact the researcher by email and say that you would like to withdraw. Any information that you have supplied will be deleted: this includes the audio-recording and the online questionnaire data you completed prior to the interview.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing the researcher's contact details.

What happens next and who can I contact about the research?

If you would like to participate in this research please complete the below questions, indicating that you understand the aims of the research, the potential risks and the procedure of the research study. You will then be required to give your consent to participate in the study by checking a box in the online questionnaire.

After you have given consent, you will be asked to complete some short demographic questions. The researcher will then be in contact within 3 business days to organise an appropriate time and location for the interview to take place.

If you have any further questions related to the study, you can contact:

Name: Caitlin Liddelow

Email: caitlin.liddelow@postgrad.curtin.edu.au

OR

Name: Barbara Mullan

Email: barbara.mullan@curtin.edu.au

Phone: (08) 9266 2468

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2017-0173). 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.

Appendix I

Participant Consent Form – Chapter 4

Project Title: How medication regimes, side effects and motivations influence medication adherence behaviours: A qualitative study

HREC project number: HRE2017-0173

Principle Investigator: Associate Professor Barbara Mullan

Co-Investigators: Dr Mark Boyes

Student researcher: Caitlin Liddelow

Version number: 1

Version date: 12/03/2019

Declaration by Participant

Please indicate that you understand each of the below statements:

I understand that this project has been approved by Curtin University Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research.

I will be audio-recorded

I will receive summary of my interview to which I can provide feedback and recommend any changes

Any identifying information will be removed after I have approved the summary of my interview

I will not be identifiable in the final write-up or presentation of findings

I may terminate the interview at any stage without repercussions

I can withdraw my data at any time prior to analysis (while it is still identifiable)

This project has been approved by the Curtin University Human research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research

- I understand the above
 I do not understand the above

I have received information regarding this research. I believe I understand the purpose, extent and possible risks of my involvement in this project and I voluntarily consent to take part.

- Yes
 No

Appendix J

Demographics Survey – Chapter 4

Participants will be asked to complete the below questions on Qualtrics after giving consent to participate, but prior to initial contact with the researchers and the interview.

1. What is your preferred name?

2. Please provide your email address so an equally appropriate time can be arranged for your interview. This email address will also be used to send the summary of your interview.

3. What is your age in years? Please type in numbers

4. How do you identify?
 - a. Male
 - b. Female
 - c. Other gender
5. How would you predominantly describe yourself?
 - a. Asian or Pacific Islander
 - b. Aboriginal or Torres Strait Islander
 - c. Caucasian
 - d. European
 - e. Middle Eastern
 - f. Other, please specify: _____
6. How many different medications do you take? Please type in numbers (e.g. 3)

Appendix K

Interview Schedule – Chapter 4

- Interviewer obtains consent to audio-record the interview.
 - Interviewer also re-iterates that the study is voluntary; the participant does not need to answer a question if he/she does not want to, and that he/she can also withdraw at any time without penalty.
 - Rapport will be built prior to asking participant first question.
 - Participant will have to complete consent and demographics on Qualtrics prior to interview
1. Can you begin by telling me about your current medication usage and needs?
 - a. Can you tell me what each of these medications is for and how they are taken?
 - b. Do you have a set routine for taking these?
 - c. Do you find them easy or hard to take?

 2. How do you feel about taking these medications?
 - a. Can you tell me why/why not you think taking medication is important?
 - b. How do your friends and family feel about you taking these medications?
 - c. Can you tell me about your motivations for adhering or not-adhering to your medication?
 - d. What do you think would happen if you didn't take your medication?
 - e. Is there a medication you take that you think is more important than the others?
 - a. Why?

 3. How would you describe your overall adherence to these medications?
 - a. Do you take them as you have been directed by your health professional?
 - b. Sometimes people simply forget to take their medication, do you sometimes experience this?
 - c. People also deliberately sometimes do not take their medication, do you sometimes do this?
 - i. If so, why?
 - d. What are some things that make it easier for you to take your medication?
 - i. Are there any particular things or techniques you have in place to assist you?
 - e. Is there anything that makes it a bit harder? Such as things that get in the way of you taking your medication correctly
 - i. Can you please tell me about them – how influential are they?
 - ii. Is there anything that could be improved that would change this? E.g. cost of medication
 - iii. What do you think would assist you in improving your adherence?

 4. What is your experience of side-effects from medication?
 - a. Please elaborate – type, number, when
 - b. Did this influence your views/motivations for taking medication?
 - c. Did it influence your adherence? How?

Appendix L

Permission to Include Copyrighted Article in Thesis – Chapter 4

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Appendix M

Co-Authors Approval to Include Paper in Thesis – Chapter 4

Signature needed for qualitative medication adherence study - inclusion in thesis 3  

 **Hannah McBride** <hannah.mcbride@live.com>
Wed 27/01/2021 23:15     
To: Caitlin Liddelow

 Statement of Contribution - A...
38 KB

Hi Cait,

As requested :)

I, Hannah McBride, give Caitlin Liddelow permission to include the article "Liddelow, C., Mullan, B., Boyes, M. & McBride, H. (2020). A qualitative application of temporal self-regulation theory to understand adherence to simple and complex medication regimens. *Healthcare*, 8(4), 487" in their PhD thesis. I am a co-author of this journal article.

Appendix N

Participant Information Sheet – Chapter 5



Participant Information Sheet

Dear Participant,

My name is Caitlin Liddelow and I am a PhD student in the School of Psychology at Curtin University in Perth, Western Australia. I am being supervised by Professor Barbara Mullan and Dr Mark Boyes from the School of Psychology. Together, we are exploring some of the influences of the oral contraceptive pill adherence.

We would like to invite you to participate in this research study that aims to understand the influence that knowledge has on adherence to the oral contraceptive pill. The overall aim of the study is to understand how particular factors influence adherence and it is hoped that this information can one day be included in interventions to improve adherence to the oral contraceptive pill.

What does it involve and how can you take part?

To take part in this study you must be a mature minor (over the age of 16 years) and be able to understand the English language. If you agree to take part in the study, by checking the box at the start of the questionnaire, you will be guided through the questionnaire which contains questions related to your use of the oral contraceptive pill, questions related to sex, children and other forms of contraception, knowledge of the oral contraceptive pill and how you take the oral contraceptive pill.

How much of your time will participation involve?

The questionnaire should take you no longer than 10 minutes to complete. There is no follow-up.

Will your participation in the project remain confidential?

If you agree to take part, you will be required to enter your worker ID so you can be paid after completing the questionnaire. Once you have been paid, your worker ID will be removed from the data. You can be confident that if you take part in the study you will remain anonymous and the information you provide will not be disclosed to other parties, only the research team will see your individual answers. Electronic data will be password-protected on Qualtrics and the Curtin University research drive. The information collected will be kept for 7 years after the research has ended. It will then be destroyed. The results of this study may be presented at conferences or published in professional journals. We will not use any identifying information in any published materials.

What are the advantages of taking part?

The information collected will be used to help us understand the ways that psychological factors can influence medication adherence. As per CloudResearch, you will receive monetary reimbursement for your participation in the study.

What are the disadvantages of taking part?

We do not believe there are any risks to you from participating in the research. However, sometimes the questions can trigger emotions. If you do experience any distress from any of the questions many online resources are available including:

- Suicide Prevention Lifeline: <https://suicidepreventionlifeline.org/>
- National Alliance on Mental Illness (NAMI) <https://www.nami.org/#>
- I'm Alive <https://www.imalive.org/>
- Planned Parenthood <https://www.plannedparenthood.org>

Do you have to take part in the study?

No, participation in this study is entirely voluntary. If you do not wish to participate you are free to discontinue with the study at any time if you change your mind. However, if you do not enter the completion code you will not be compensated.

Who can I contact if I have any questions or concerns?

If you have any questions, please do not hesitate to contact us:

Caitlin Liddelow at caitlin.liddelow@postgrad.curtin.edu.au or

Professor Barbara Mullan at barbara.mullan@curtin.edu.au. Phone: +61 08 9266 2468

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2017-0173). Should you wish to discuss the study with someone not directly involved, in particular that of 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

Appendix O

Qualtrics Survey – Chapter 5

Consent

Q1 Do you consent to participate in this study?

- Yes
- No

Q2 Please enter your worker ID so you can be reimbursed for your time

Demographics

Q1 Do you currently use/take the oral contraceptive pill?

- Yes
- No

Q2 How do you identify?

- Female
- Male
- Another gender - please specify _____

Q3 What type of oral contraceptive pill do you use?

- Combination pill - These are used in one-month cycles and each active pill gives you a dose of hormone. During the last week of the cycle, you take inactive pills and have your period.
- Combination pill - extended cycle - These are typically used in 13-week cycles. You take active pills for 12 weeks, and during the last week of the cycle, you take inactive pills and have your period. As a result, you have your period only three to four times per year.
- Progestin-only pill / Mini pill - With these progestin-only pills, all pills in the cycle are active. There are no inactive pills, so you may or may not have a period while taking progestin-only pills.
- Unsure

Q4 What is the name of the oral contraceptive pill you are currently using? Please select one

- Alesse
- Apri
- Aranelle
- Aviane
- Brenda
- Camila
- Enpresse
- Errin
- Estrostep
- Lessina
- Jolivette
- Levlen
- Levlite
- Levora
- Loestrin
- Lybrel
- Mircette
- Micronor
- Natazia
- Nordette
- Lo/Orval
- Ortho-Novum
- Ortho Tri-Cyclen
- Seasonale
- Seasonique
- Yasmin
- Yaz
- Other, please specify _____

Q5 How long have you been using the oral contraceptive pill?

- Number of years or, _____
- Number of months _____

Q6 What is your main reason for using the oral contraceptive pill?

- Contraception
- Acne/Skin problems
- To regulate periods
- Menstrual cramps or endometriosis
- Polycystic Ovary Syndrome (PCOS)
- Other, please specify _____

Q7 Do you experience side effects from using the oral contraceptive pill? If yes, please specify

- No
- Yes _____
- Unsure

Q8 Are you sexually active?

- Yes
- No
- Don't want to say

Q9 How did you select this method of contraception? (oral contraceptive pill)

- Advised by general physician (doctor)
- Advised by gynaecologist
- Own preference (but received prescription from doctor)
- Do not remember
- Other, please specify _____

Q10 Have you ever been pregnant?

- Yes
- No
- Don't want to say

Q11 Have you ever used emergency contraception (e.g. the morning after pill)?

- Yes
- No
- Don't want to say

Q12 How many children do you have? Please write as a number (e.g. 0)

Q13 Were you given instructions about the method of using the oral contraceptive pill by your doctor?

- Yes
- No
- Not Sure

Q14 What type of instructions were you told by your doctor? Select all that apply

- Take one pill every day
- If you experience side effects you are worried about, go back to your doctor
- Additional contraception may be required if you miss a pill
- Take the pill at the same time every day
- Other, please specify _____

Q15 Did you read the instructions inside the pill package?

- Yes
- No
- Not Sure

Q16 How much do you agree with the following statement "I have adequate knowledge about the correct use of the oral contraceptive pill"?

- Strongly agree
- Agree
- Somewhat agree
- Not sure
- Not at all

OCP Usage Behaviour

Q1 At what time of the day do you usually take your oral contraceptive pill?

- Morning
- Afternoon
- Evening
- Bedtime
- When I remember

Q2 Can you please tell us how you remember to take your oral contraceptive pill?

Q3 Have you ever missed taking the oral contraceptive pill on a day where you were supposed to take it?

- Yes
- No
- Not sure/cannot remember

Q4 How many times did you miss your oral contraceptive pill in the previous month even if you remembered later and took two pills in the same day)?

- 0
- 1
- 2+ times a month

Health Literacy Skills Instrument

Question 1

(Answer: B)

Please answer the following question based on the information in the text

Cholesterol: What Your Level Means	Total cholesterol level
<p>What is cholesterol?</p> <p>Cholesterol is a waxy substance the body uses to protect nerves, make cell tissues and produce certain hormones.</p> <p>Are there different types of cholesterol?</p> <p>Yes. Cholesterol travels through the blood in different types of packages, called lipoproteins.</p> <p>Low-density lipoproteins (LDL) deliver cholesterol to the body. High-density lipoproteins (HDL) remove cholesterol from the bloodstream.</p>	<ul style="list-style-type: none"> • Less than 200 is best. • 200 to 239 is borderline high. • 240 or more means a person is at increased risk for heart disease. <p>LDL cholesterol levels</p> <ul style="list-style-type: none"> • Below 100 is ideal for people who have a higher risk of heart disease. • 100 to 129 is near optimal. • 130 to 159 is borderline high. • 160 or more means a person is at a higher risk for heart disease. <p>HDL cholesterol levels</p> <ul style="list-style-type: none"> • Less than 40 means a person is at higher risk for heart disease. • 60 or higher greatly reduces a person's risk of heart disease.

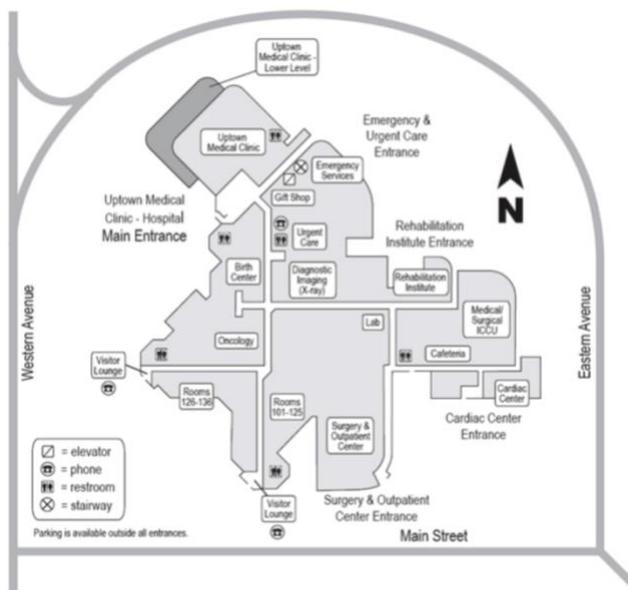
Which set of low density lipoprotein (LDL) and high density lipoprotein (HDL) levels is best?

- LDL of 134 and HDL of 61
- LDL of 98 and HDL of 82
- LDL of 140 and HDL of 50
- LDL of 165 and HDL of 80
- Not sure

Question 2

(Answer: D)

Please answer the following question based on the information in the map



Which of the following entrance is closest to the elevator?

- There is no elevator
- Surgery & Outpatient Center Entrance
- Rehabilitation Institute Entrance
- Main Entrance
- Don't Know

Question 3 (Answer: C)

Please answer the following question based on the information in the chart

Be an Active Member of Your Health Care Team
My Medicine Record

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Food and Drug Administration 

Name (Last, First, Middle Initial): _____ Birth Date (mm/dd/yyyy): _____

	What I'm Using Rx – Brand & generic name; OTC – Name & active ingredients	What It Looks Like Color, shape, size, markings, etc.	How Much	How to Use / When to Use	Start / Stop Dates	Why I'm Using / Notes	Who Told Me to Use / How to Contact
<i>— Enter ALL prescription (Rx) medicine (include samples), over-the-counter (OTC) medicine, and dietary supplements —</i>							
Ex:	XXXX/XXXXXXXX	20 mg pill; small, white, round	40 mg; use two 20 mg pills	Take orally, 2 times a day, at 8:00 am & 8:00 pm	1-15-11	Lowers blood pressure; check blood pressure once a week; blood test on 4-15-11	Dr. X (800) 555-1212
1							
2							
3							
4							
5							
6							
7							
8							

www.fda.gov/Drugs/ResourcesForYou/ucm079489.htm (888) INFO-FDA www.fda.gov/usemedicinesafely These are my medicines as of (Enter date as mm/dd/yyyy): _____

In the example listed in the first row of the table, when should the medicine be taken?

- Two times a day anytime between 8 a.m. and 8 p.m.
- At 8 a.m. or 8 p.m. each day
- At 8 a.m. and 8 p.m. each day
- Don't Know

Question 4 (Answer: B)

Please read the question below, then visit the following website to answer the question. Answer the questions based on the information in the website.

<https://www.cardiosmart.org/healthwise/tx43/94/tx4394>

Kate weighs 150 pounds. Which activity would burn the most calories?

- Walking at a medium pace for 30 minutes
- Raking the lawn for 30 minutes
- Bowling for 30 minutes
- Don't Know

(website from above link)

The screenshot shows the website cardiosmart.org/healthwise/tx43/94/tx4394. The navigation bar includes: Heart Conditions, Drugs and Treatments, Heart Basics, Healthy Living, News and Events, Find A Hospital, and My Dashboard. The main content area is titled "Interactive Tools" and features a tool titled "Interactive Tool: How Many Calories Did You Burn?". The tool's description states: "Click here to find the number of calories you burn during exercise and daily physical activities." Below this is a "START" button. To the right, under "Topic Contents", there are links for: "What does this tool measure?", "Health Tools", "What do the results mean?", "What's next?", "Related Information", "References", and "Credits". A brief explanation follows: "This interactive tool estimates how many calories are burned during common activities. The food you eat is measured in calories. The energy you use every day is also measured in calories. You are using energy all the time, even at rest. The more vigorous the activity and the longer the time you do it, the more calories you burn. This tool also uses your weight to calculate calories burned, because a heavier person burns more calories during activity than a lighter person."

Question 5 (Answer: A)

Please answer the following question based on the information in the flyer

Signs of a Stroke

My mother is alive today because a police officer knew the signs of a stroke. You can save a life, too, if you learn these signs.

Mom was on her way to the dentist when a police officer noticed she was driving strangely and started to follow her. She pulled over on the highway. When the officer approached her, she told him she had a blinding headache. But she said that she had to get to her dentist appointment on time.

The officer also noticed that mom just wasn't acting right. Some of her speech was confused. And she was a little dizzy.

Mom said she felt fine, but that didn't stop the officer. He quickly called 911. That call saved my mother's life.

Knowing the signs of a stroke could help you save a life, too. Remember, some people have all of these signs, but my mom only had a few.

If you or someone else has even a few of these signs, get help fast!

Five Signs of a Stroke

- Sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- Sudden confusion, trouble speaking or understanding
- Sudden trouble seeing in one or both eyes
- Sudden trouble walking, dizziness, or loss of balance
- Sudden, severe headache

American Stroke Prevention

Which of the following is NOT a sign of a stroke?

- Shaking chills
- Blurred vision
- Bad headache
- Numbness on one side
- Don't know

Question 6 (Answer: A)

Please answer the following question based on the information in the text and charts

Portion Control for Weight Loss Expanding portions

Are you eating a variety of healthy foods, exercising and still struggling with your weight? Some people may need to pay closer attention to portion control — managing the amount of food that they eat — as their total calorie intake determines their weight.

A serving isn't what they happen to put on their plate. It's a specific amount of food defined by common measurements, such as cups, ounces or pieces. The serving sizes represented here are part of the Mayo Clinic Healthy Weight Pyramid — a food pyramid designed to promote weight loss and long-term health. Use these serving sizes in conjunction with a diet based on a variety of healthy foods. Add the right amount of regular physical activity, and a person will be well on their way to enjoying good nutrition and controlling their weight.

Vegetables

Until they're comfortable judging serving sizes, you may need to use measuring cups and spoons. A half a cup of cooked carrots, for example, equals one serving. Here are the recommended serving sizes for other vegetables:

Food	Serving size
Raw leafy vegetables	= 2 cups
Raw vegetables, chopped	= 1 cup
Chopped, cooked or canned vegetables	= 1/2 cup



Meat and beans

Familiar objects can help a person picture proper portions for meat, poultry, fish and beans. For example, a 3-ounce serving of fish is about the size of a deck of cards. Here are the serving sizes for meat and meat substitutes:

Food	Serving size
Cooked skinless poultry or fish	= 3 ounces
Cooked lean meat	= 1 1/2 ounces
Cooked legumes or dried beans	= 1/2 cup or about the size of an ice cream scoop
Egg	= 1 medium



A person is cooking dinner for himself and he wants to include one serving from the meat and beans group. What should he choose?

- 1 ½ ounces of cooked lean beef
- 1 ½ ounces of cooked fish
- 3 boiled eggs
- 1 cup of cooked kidney beans
- Don't Know

Question 7 (Answer: C)

Please answer the following question based on the information in the video clip.

[Lunges video](#)

What parts of the body do lunge exercises work?

- Arms and shoulders
- Back and abdomen
- Legs and buttock
- Don't Know

(website from above link)

mayoclinic.org/healthy-lifestyle/fitness/multimedia/lunge/vid-20084662

Understanding the... Understanding the... IWannaTicket :: Win... Preliminary examin...

Healthy Lifestyle Fitness

Basics In-Depth Expert Answers **Multimedia** Resources News From Mayo Clinic What's New

Products and services

The Mayo Clinic Diet
What is your weight-loss goal?

- 5-10 lbs »
- 11-25 lbs »
- 25+ lbs »

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Video: Lunge exercise



Dr. Laskowski: The lunge is a body resistance exercise that works the leg muscles. Specifically, the lunge targets the quadriceps and the hamstring muscles in the thigh, the gluteal muscles in the buttock, and to a lesser extent, the lower leg muscles. The lunge is a great conditioning exercise for many sports, especially those that involve lunging movements, such as tennis, basketball or soccer.

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Question 10 (Answer: C)

Please answer the following questions based on the information in the audio clip



If a person was worried about his cough, what number should he press?

- 1
- 2
- 4
- Call 911
- Not sure

Oral Contraceptive Pill Knowledge

Q1 Please select whether you think the following statements are TRUE or FALSE

	True	False
You cannot get sexually transmitted infections while taking the pill	<input type="radio"/>	<input type="radio"/>
If taken correctly, the pill is very good at NOT preventing you from pregnancy	<input type="radio"/>	<input type="radio"/>
The pill has either a combination of estrogen and progestin or progestin only	<input type="radio"/>	<input type="radio"/>
It is really hard to become pregnant after you stop taking the pill	<input type="radio"/>	<input type="radio"/>
The pill works partly by keeping the ovaries from releasing an egg each cycle	<input type="radio"/>	<input type="radio"/>
The regular use of certain medications can reduce how well the pill works	<input type="radio"/>	<input type="radio"/>
The pill contains hormones that are very different from those made by a woman's body	<input type="radio"/>	<input type="radio"/>
The pill is a daily hormonal contraceptive	<input type="radio"/>	<input type="radio"/>
There is more health risk with being pregnant than with taking the pill	<input type="radio"/>	<input type="radio"/>
The pill works partly by thickening the mucus in the cervix so sperm cannot get into the uterus (womb)	<input type="radio"/>	<input type="radio"/>

Q2 Please select whether you think the pill makes each symptom better, worse, or has no effect

	Better	Worse	No effect
Acne	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Menstrual cramps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Irregular periods	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Heavy periods	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Weight gain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q3 Please select whether you think the pill makes each condition increase, decrease or has no effect

	Increases	Decreases	No effect
Ovarian cancer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Blood clots	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pelvic inflammatory disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Stroke	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ovarian cysts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non-cancerous breast tumours	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anaemia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Heart attack	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ectopic pregnancy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Uterine cancer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q4 For each health problem, select what you would do about taking the pill AND about telling your doctor

	Would you stop taking or continue taking the pill?		Would you call your doctor immediately, discuss at the next visit or not tell?		
	Stop taking	Continue taking	Call immediately	Discuss at next visit	Not tell
Nausea	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Leg pain or swelling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble breathing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Spotting between periods	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chest pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Breast tenderness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
New breast lump	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Yellowing of skin/eyes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Medication Adherence Report Scale (MARS-5)

Q1 Please rate how much each of the below statements describes your oral contraceptive pill use in the previous month

	Never	Sometimes	About half the time	Most of the time	Always
I forgot to take my oral contraceptive pill	<input type="radio"/>				
I altered the dose of my oral contraceptive pill	<input type="radio"/>				
I stopped taking my oral contraceptive pill for a while when I was not supposed to	<input type="radio"/>				
I decided to miss out a dose of my oral contraceptive pill	<input type="radio"/>				
I took less than instructed	<input type="radio"/>				

Timeline Follow-Back

Q1 The below question will ask you about your PREVIOUS WEEK rather than your PREVIOUS MONTH.

Please provide accurate information. This will help you reconstruct your LAST week, not the average week. It is important for you to try and remember what was not usual during the previous week (you felt sick, attended a party, travelled, been at work longer hours etc.) and how this impacted correctly taking your oral contraceptive pill.

Using the below calendar, please reconstruct the use of your oral contraceptive pill in the past week and what events impacted this, if any. The following are instructions and tips for completing the record:

1. In the first row, please enter the day (e.g. Wednesday) and the date (02/01) for the previous seven days.
2. In the second row, please enter any special events (if any) that occurred on that day. If none, please leave blank.
3. In the third row, please enter a Y if you took your oral contraceptive pill or an N if you did not take it on that day.
4. In the bottom row, please enter a Y if you took your oral contraceptive pill as prescribed by your doctor on that day (e.g. in the morning or at a specific time). If you did not take it as prescribed, please enter an including if you entered an N in the row above.

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Day/date (e.g. Monday 7/5/18)							
Did you have any special events this day? Please specify							
Did you take your pill today?							
Did you take your pill as prescribed by your doctor?							

General Demographics

Q1 What is your age? Please write in numbers (e.g. 32)

Q2 What is your personal annual income in USD?

- Less than \$18,000
- \$18,000 - \$35,000
- \$35,000 - \$55,000
- \$55,000 - \$75,000
- \$75,000 - \$90,000
- More than \$90,000

Q3 What is the highest level of education you have achieved? If currently enrolled, highest degree received

- No schooling completed
- Elementary school
- Secondary school, high school, diploma or equivalent (e.g. GED)
- Some college, no degree
- Bachelor's Degree (e.g. BA, BS)
- Postgraduate Degree (e.g. Masters)
- Professional degree (e.g. MD, DDS, DVM)
- Doctorate (e.g. PhD, EdD)
- Trade/technical/vocational training

Q4 How would you predominantly describe yourself?

- African American
- Hispanic or Latinx
- American Indian or Alaska Native
- Caucasian
- Asian
- Native Hawaiian or Other Pacific Islander
- European
- Middle Eastern
- Other _____

Appendix P

Permission to Include Copyrighted Article in Thesis – Chapter 5

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Adherence to the oral contraceptive pill: the roles of health literacy and knowledge

Caitlin Liddelow , Barbara Mullan & Mark Boyes

Pages 587-600 | Received 17 Aug 2020, Accepted 10 Nov 2020, Published online: 01 Dec 2020

[Download citation](#) <https://doi.org/10.1080/21642850.2020.1850288> [Check for updates](#)

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Appendix Q

Ethics Approval Letter – Chapter 6



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

30-Jun-2020

Name: Barbara Mullan
Department/School: School of Psychology
Email: Barbara.Mullan@curtin.edu.au

Dear Barbara Mullan

RE: Amendment approval
Approval number: HRE2020-0158

Thank you for submitting an amendment request to the Human Research Ethics Office for the project **Feasibility study to explore the mechanisms of habit formation for taking the oral contraceptive pill**.

Your amendment request has been reviewed and the review outcome is: **Approved**

The amendment approval number is HRE2020-0158-01 approved on 30-Jun-2020.

The following amendments were approved:

To add 3 additional questions to the final (third) follow-up survey.

Special Condition of Approval

It is the responsibility of the Chief Investigator to ensure that any activity undertaken under this project adheres to the latest available advice from the Government or the University regarding COVID-19.

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

Appendix R

Participant Information Sheet – Chapter 6



Feasibility study to explore the mechanisms of habit formation for taking the oral contraceptive pill

Who is doing the Research and What is the Project About?

My name is Caitlin Liddelow and I am a PhD student in the School of Psychology at Curtin University. I am being supervised by Professor Barbara Mullan and Dr Mark Boyes from the School of Psychology. We would like to invite you to participate in this research study that aims to explore and understand the underlying mechanisms that can help make taking the daily oral contraceptive pill (the pill) a habit. It is hoped that one day this information can be provided to women who take the pill to improve their adherence and reduce any negative consequences that can result if it is not taken correctly.

Why am I being asked to take part and what will I have to do?

We are inviting young women (below the age of 35 years) who currently take the pill (either the combined pill, or the mini-pill/progestogen only) for contraception but are not very good at remembering to take it. Your participation will require you to be involved in a 10-week study where you will complete a short questionnaire at four different times: at the beginning of the study, at the end of the study (6 weeks), a follow-up 2-weeks after the end of the study and finally, another follow-up 2-weeks after this. We will ask you questions about your current pill taking behaviour, as well as general demographics. Each questionnaire should take you no longer than 15 minutes. For this study, you will only be required to participate for approximately a total of 1 hour over the 10-weeks.

Once you have read this information sheet you will be asked to provide informed consent. This will mean that you have understood what is in this sheet and agree to participate in the study. After that, you will be asked to complete the first questionnaire, create a participant ID and provide your email address, so you can be contacted to complete the questionnaires. Your email address will also be how we contact you if you win a prize. After doing this, you will be randomly assigned to one of four groups. For this study, you will only be required to take your oral contraceptive pill and read your emails. However, depending on which of the four groups you are randomised to, you may receive some more specific instructions. Once all four questionnaires have been completed, if you are participating for course credits at Curtin University, you will receive 4 SONA participation points. If you are not participating for course credit points, you will be entered into the draw to win 1 of 5 \$50 Coles/Myer shopping vouchers.

Are there any benefits to being in the research project?

You may learn some new techniques to assist you in taking your pill. You may also have an increased knowledge of how the pill works.

Are there any risks, side-effects, discomforts or inconveniences from being in the research project?

It is unlikely that this study poses a risk to you if you participate. However, sometimes questions can trigger emotions. If at any stage you experience unwanted emotions, please contact the researchers who will provide you with a fact sheet about the pill as well as some online resources and organisations you can contact to talk about your concerns. If at any stage you feel uncomfortable about participating, you can voluntarily withdraw your consent. If you do withdraw, you will not be penalised and your relationship with the researchers or the University will not be affected. However, you will not be eligible for the SONA participation points if you are participating for course credits or to be entered into the prize draw.

If you do experience any distress from any of the questions many online resources are available including:

- Lifeline (13 11 14): www.lifeline.org.au
- Family Planning NSW Talkline: <https://www.fpnsw.org.au/talkline>
- Sexual Health Quarters: www.shq.org.au
- Healthy WA: www.healthywa.health.wa.gov.au/

Who will have access to my information?

The information collected in this research will be re-identifiable (coded). This means that we will collect data that can identify you (e.g. email and student ID if from Curtin University). The email address you provide will be used to contact you if you win a prize. Once all prizes have been drawn, at the end of data collection, your email address and other identifying information will be removed and replaced with your ID code for analysis. You can be confident that if you participate in this study, the information you provide will not be disclosed to other parties, only the research team will see your individual answers. The research team will keep all of your information private and confidential. Electronic data will be password-protected on Qualtrics and the Curtin University research drive for 7-25 years (due to conducting research where the projects involve children [-18 years]) after the research has ended. It will then be destroyed. 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.

Do I have to take part in the research project?

Taking part in a research project is completely voluntary. It is your choice to take part or not. If you decide to take part and then change your mind, that is okay, you can withdraw from the project. This will not affect your relationship with the researchers or the University. However, if you do decide to stop the study you will not be eligible to receive the SONA points or be entered into the prize draw. If you choose to leave the study, we will use the information that you have provided to that point, unless you tell us not to.

What happens next and who can I contact about the research?

If you have any questions or require any further information, please contact the researchers.

Professor Barbara Mullan at barbara.mullan@curtin.edu.au or (08) 9266 2468 or

Dr Mark Boyes at mark.boyes@curtin.edu.au or (08) 9266 7025 or
Caitlin Liddelow at caitlin.liddelow@postgrad.curtin.edu.au

If you decide to take part in this research we will ask you to tick the consent box below. By ticking it you are telling us that you understand what you have read and what has been discussed. Ticking the consent box indicates that you agree to be in the research project and have your information used as described.

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2020-0158). 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.

Appendix S

Intervention Condition Information/Instructions – Chapter 6

Control Group

Thank you for volunteering to be part of this study and for completing the first questionnaire. For the next 6 weeks please ensure you take your oral contraceptive pill as you currently normally would. You are not required to change anything. The researchers will contact you at the end of the 6 weeks to ask you some questions. Please keep an eye out on your email.

Experimental Group 1 – Information Only

Thank you for volunteering to be part of this study and for completing the first questionnaire. Please read the following oral contraceptive pill information sheet and for the next 6 weeks try and take your oral contraceptive pill according to this information sheet. You are not required to do anything else. The researchers will contact you at the end of the 6 weeks to ask you some questions. Please keep an eye out on your email.

Experimental Group 2 – Cue Only

Thank you for volunteering to be part of this study and for completing the first questionnaire. A cue is something that prompts a behaviour. Can you please spend the next few minutes thinking of a cue that you can match to your oral contraceptive pill, to assist you in remembering to take your pill. It can be anything that you do every day. For example, you may choose brushing your teeth before bed, or placing your pill box on your bedside table so you see it every morning when you wake up. We would like you to pair this cue with you taking your oral contraceptive pill. For the next 6 weeks try and take your daily oral contraceptive pill when you see or experience your chosen cue. The researchers will contact you at the end of the 6 weeks to ask you some questions. Please keep an eye out on your email.

Experimental Group 3 – Information + Cue

Thank you for volunteering to be part of this study and for completing the first questionnaire. Please read the following oral contraceptive pill information sheet and after, spend the new few minutes thinking of a cue that you can match to your oral contraceptive pill, to assist you in remembering to take your pill. A cue is something that prompts a behaviour. It can be anything that you do every day. For example, you may choose brushing your teeth before bed, or placing your pill box on your bedside table so you see it every morning when you wake up. We would like you to pair this cue with you taking your oral contraceptive pill. For the next 6 weeks try and take your daily oral contraceptive pill when you see or experience your chosen cue. The researchers will contact you at the end of the 6 weeks to ask you some questions. Please keep an eye out on your email.

Appendix T

Intervention Materials (Consumer Medicine Information Leaflet) – Chapter

6

Combination Pill

LEVLEN® ED

(Lev-Ien Ee-Dee)

Contraceptive tablets for women

ethinylestradiol and levonorgestrel

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Leven ED. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Leven ED against the benefits they expect it will have for you.

If you have any concerns, or are unsure about taking this medicine, ask your doctor or pharmacist for more advice.

Keep this leaflet with the medicine.
You may need to read it again.

WHAT LEVLEN ED IS USED FOR

Leven ED is a combined oral contraceptive, commonly known as a 'birth control pill' or 'the Pill'.

Leven ED is used to prevent pregnancy.

You may also experience the following benefits:

- more regular and lighter periods – potentially resulting in a

decrease in anaemia (iron deficiency)

- a decrease in period pain.

Some conditions such as pelvic inflammatory disease, ovarian cysts, ectopic pregnancy (where the foetus is carried outside of your womb), lumpy breasts, acne and cancer of the uterus (womb) and ovaries may be less common in women taking the Pill.

When taken correctly, Leven ED prevents you from becoming pregnant in several ways, including:

- inhibiting ovulation (egg release)
- changing the cervical mucus consistency, making it more difficult for the sperm to reach the egg
- changing the lining of the uterus, making it less suitable for implantation.

When the Pill is taken by women under close observation in clinical trials, it is more than 99% effective in preventing pregnancy. However, in real life the Pill is around 92% effective. This is because pills might have been missed, may have been taken with medicines that interfere with their effectiveness, or may not be absorbed due to vomiting or diarrhoea.

Like all oral contraceptives, Leven ED is intended to prevent

pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted infections.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE LEVLEN ED

When you must not take it

Do not take Leven ED if you have an allergy to:

- ethinylestradiol and/or levonorgestrel (the active ingredients in Leven ED)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Leven ED if you have or have had a blood clot in:

- the blood vessels of the legs (deep vein thrombosis - DVT)
- the lungs (pulmonary embolism - PE)

- the heart (heart attack)
- the brain (stroke)
- other parts of the body.

Do not take Leven ED if you have or are concerned about an increased risk of blood clots.

Blood clots are rare. Very occasionally blood clots may cause serious permanent disability, and may even be fatal.

You are more at risk of having a blood clot when you take the Pill. However, the risk of having a blood clot when taking the Pill is less than the risk of having a blood clot during pregnancy.

Do not take Leven ED if you are concerned about an increased risk of blood clots because of age or smoking.

The risk of having a heart attack or stroke increases as you get older. It also increases if you smoke.

You should stop smoking when taking the Pill, especially if you are older than 35 years of age.

Do not take Leven ED if you are taking any antiviral medicines which contain ombitasvir, paritaprevir and/or dasabuvir. These antiviral medicines are used to treat chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus (HCV)).

Do not take Leven ED if you have, or have had:

- any blood clotting disorders such as Protein C deficiency, Protein S deficiency, Leiden Factor V mutation, Antithrombin III deficiency or other inherited blood clotting conditions
- a confirmed blood test showing:
 - increased levels of homocysteine

- antiphospholipid antibodies (APLAs) e.g. anticardiolipin-antibodies and lupus anticoagulant. These may increase your risk for blood clots or pregnancy losses (miscarriage)

- major surgery after which you have not been able to move around for a period of time
- angina (chest pain)

- a mini-stroke (also known as TIA or transient ischaemic attack)

- migraine, where you have also had problems with seeing, speaking or had, or weakness or numbness in any part of your body

- high risk of blood clots due to conditions such as diabetes with blood vessel damage, severe high blood pressure or severe high or low level of fats in your blood

- pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood

- severe liver disease and your liver function has not returned to normal

- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)

- a benign or malignant liver tumour
- unexplained vaginal bleeding.

If any of these conditions appear for the first time while using the Pill, stop taking it at once and tell your doctor. In the meantime, use non-hormonal (barrier) methods of contraception (such as condoms or a diaphragm).

Do not take this medicine if you are pregnant or think you might be pregnant.

Do not give this medicine to a child.
Leven ED is not intended for use in females whose periods have not yet started.

Do not take this medicine after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- you smoke
- you or anyone in your immediate family has had blood clots in the legs (DVT), or lungs (PE), a heart attack, a stroke, breast cancer or high cholesterol.

Tell your doctor if you have, or have had any of the following medical conditions:

- diabetes
- high blood pressure
- heart valve disorders or certain heart rhythm disorders
- migraine
- cancer
- hyperhomocysteinaemia, a condition characterised by high levels of the amino acid homocysteine in the blood
- high or low level of fats in your blood.

Ask your doctor to check if you:

- are overweight
- have any hereditary or acquired conditions that may make it more likely for you to get blood clots
- have high cholesterol or triglycerides
- have liver disease
- have gall bladder disease
- have jaundice (yellowing of the skin) and/or pruritus (itching of the skin) related to cholestasis (condition in which the flow of bile from the liver stops or slows)
- have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- have systemic lupus erythematosus (SLE – a disease affecting the skin all over the body)
- have haemolytic uraemic syndrome (HUS – a disorder of blood coagulation causing failure of the kidneys)
- have sickle cell disease
- have a condition that occurred for the first time, or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called herpes gestationis, a neurological disease called Sydenham's chorea)
- have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid exposure to the sun or ultraviolet radiation
- have hereditary angioedema – you should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue and/or pharynx and/or difficulty swallowing, or hives together with difficulty in breathing.

If any of the above conditions appear for the first time, recur

or worsen while taking Leven ED, you should tell your doctor.**Tell your doctor if you are breastfeeding.**

Leven ED is generally not recommended if you are breastfeeding.

Leven ED contains lactose.

If you have an intolerance to some sugars, tell your doctor before you start taking Leven ED.

If you have not told your doctor about any of the above, tell him/her before you start taking Leven ED.**Taking other medicines**

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Leven ED may interfere with each other. These include:

- medicines used to treat tuberculosis such as rifampicin, rifabutin
- a class of antibiotics known as macrolides, such as clarithromycin, erythromycin
- medicines used to treat fungal infections, such as ketoconazole, griseofulvin
- medicines used to treat HIV, such as ritonavir, nevirapine
- some medicines used to treat HCV, such as boceprevir, paritaprevir, dasabuvir
- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- ciclosporin, an immunosuppressant medicine

- etoricoxib, a medicine used to treat painful joint disease
- melatonin, a hormone used as a sleep aid
- midazolam, a medicine used as a sedative
- theophylline, a medicine used to treat respiratory disease
- tizanidine, a medicine used as a muscle relaxant
- some medicines used to treat high blood pressure, chest pain or irregular heartbeats such as diltiazem, verapamil
- herbal medicines containing St John's Wort
- grapefruit juice.

These medicines may be affected by Leven ED, or may affect how well it works. Your doctor may need to alter the dose of your medicine, or prescribe a different medicine.

You may need to use additional barrier methods of contraception (such as condoms or a diaphragm) while you are taking any of these medicines with Leven ED and for some time after stopping them.

Your doctor will be able to tell you how long you will need to use additional contraceptive methods.

Your doctor and pharmacist have more information on medicines that you need to be careful with or avoid while taking this medicine.

HOW TO TAKE LEVEN ED

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask

your doctor or pharmacist for help.

How to take it

Take one tablet daily at about the same time every day. You must take Leven ED every day regardless of how often you have sex. This will also help you remember when to take it.

Swallow the tablet whole with a full glass of water. It does not matter if you take it before or after food.

Each blister pack is marked with the day of the week. **Take your first tablet from the red area on the blister pack corresponding to the day of the week.**

Follow the direction of the arrows on the blister pack until all the tablets have been taken.

A period should begin 2 to 3 days after starting to take the white inactive tablets (last row) and may not have finished before the next pack is started.

Always start a new blister pack on the same day of the week as your previous pack.

Taking Leven ED for the first time

If you are starting Leven ED after a natural cycle, and you have not used a hormonal contraceptive in the past month, start on the first day of your period, i.e. the first day of menstrual bleeding.

You must also use additional barrier contraceptive precautions (e.g. condoms or a cap or diaphragm with spermicide) for the first 14 days of tablet-taking when having intercourse.

Your doctor will advise you when to start if you:

- are taking Leven ED after having a baby
- have had a miscarriage or an abortion.

Changing from another contraceptive**Changing from a combined oral contraceptive:**

Start taking Leven ED on the day after taking the last active tablet in your previous Pill pack. Bleeding may not occur until the end of the first pack of Leven ED.

If you are not sure which were the active/inactive tablets in your previous Pill pack, ask your doctor or pharmacist. Your previous Pill pack may have different colour tablets to those of Leven ED.

Changing from a vaginal ring:

Start taking Leven ED on the day of removal of the ring but at the latest when the next application would have been due.

Changing from a progestogen-only pill ('minipill'):

Stop taking the minipill on any day and start taking Leven ED at the same time the day after you took your last minipill.

You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 14 days of tablet-taking when having intercourse.

Changing from a progestogen-only injection, implant or intrauterine system (IUS):

Start taking Leven ED when your next injection is due, or on the day that your implant or IUS is removed.

You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 14 days of tablet-taking when having intercourse.

Stopping Leven ED

You can stop taking Leven ED at any time. If you are considering becoming pregnant, it is recommended that you begin taking a vitamin supplement containing folic acid. It is best that you start taking folic acid tablets before you stop taking Leven ED and not stop until your doctor advises this. Ask your doctor or pharmacist about suitable supplements. It is both safe and recommended that you take folic acid during pregnancy.

Additional contraceptive precautions

When additional contraceptive precautions are required you should either abstain from sex, or use a barrier method of contraception, a cap (or diaphragm) plus spermicide, or a condom. Rhythm methods are not advised as the Pill disrupts the cyclical changes associated with the natural menstrual cycle e.g. changes in temperature and cervical mucus.

If you forget to take Leven ED

If you miss a tablet and take the missed tablet within 12 hours of missing it, you should still be protected against pregnancy.

If you are more than 12 hours late follow these detailed instructions:

For Leven ED to be most effective, beige active tablets need to be taken uninterrupted for 7 days.

If you have been taking the beige active tablets for 7 uninterrupted days and miss a beige active tablet, take the missed tablet as soon as you remember, then go back to taking your Pill as you would normally, even if this means taking two tablets in one day, at the same time. You should still be protected against pregnancy.

The chance of pregnancy after missing a beige active tablet depends on when you missed the tablet. There is a higher risk of becoming pregnant if you miss a tablet at the beginning or end of a pack.

If after taking your missed tablet you have less than 7 days of beige active tablets left in a row, you should finish the active tablets in your pack but skip the white inactive tablets. Start taking the beige active tablets in your next pack corresponding to the correct day of the week.

This is the best way to maintain contraceptive protection. However, you may not have a period until the end of the beige active tablets of the second pack. You may have spotting or breakthrough bleeding on tablet-taking days.

If you have been taking the beige active tablets for less than 7 days and miss a beige active tablet, take the missed tablet as soon as you remember, then go back to taking your Pill as you would normally, even if this means taking two tablets in one day, at the same time. In addition, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the next 7 days.

If you have had sexual intercourse in the preceding 7 days, there is a possibility of pregnancy and you

may need emergency contraception. You should discuss this with your doctor or pharmacist.

If you forget to take more than one beige active tablet, seek advice from your doctor or pharmacist about what to do.

If you have had sexual intercourse in the week before missing your tablets, there is a possibility of becoming pregnant.

If you miss a white inactive tablet, you do not need to take them later because they do not contain any active ingredients. However, it is important that you discard the missed white tablet(s) to make sure that the number of days between taking active tablets is not increased as this would increase the risk of pregnancy. Continue with the next tablet at the usual time

Please see the table at the end of this leaflet, "Summary of advice if you missed a beige active tablet more than 12 hours ago".

Ask your doctor or pharmacist to answer any questions you may have.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26) for advice, or go to the Accident and Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much Leven ED. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

WHILE YOU ARE TAKING LEVEN ED

Things you must do

Tell any doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Have regular check-ups with your doctor. When you are taking the Pill, your doctor will tell you to return for regular check-ups, including getting a Cervical Screening Test. Your doctor will advise how often you need a Cervical Screening Test. A Cervical Screening Test can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cancer.

If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking Leven ED.

Stop taking Leven ED and see your doctor immediately if you notice the following signs:

- one-sided swelling of the leg and/or foot or along a vein in the leg
- pain or tenderness in the leg which may be felt only when standing or walking
- increased warmth in the affected leg; red or discoloured skin on the leg
- sudden onset of unexplained shortness of breath or rapid breathing
- sudden coughing or coughing up of blood
- sharp chest pain or sudden severe pain in the chest which

may increase with deep breathing

- severe light headedness or dizziness
- rapid or irregular heartbeat
- sudden pain, swelling and slight blue discoloration of an extremity
- sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- sudden confusion, slurred speech or aphasia; sudden partial or complete loss of vision, double vision, painless blurring of vision which can progress to loss of vision
- sudden, severe or prolonged headache with no known cause
- loss of consciousness or fainting with or without seizure
- pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest arm, or below the breastbone
- discomfort radiating to the back, jaw, throat, arm, stomach
- feeling of being full, having indigestion or choking
- sweating, nausea, vomiting extreme weakness and anxiety.

If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are taking Leven ED. The risk of having blood clots is temporarily increased as a result of major surgery, any surgery to the legs or pelvis, neurosurgery or major trauma. In women who take Leven ED, the risk may be higher.

In women at risk of prolonged immobilisation (including major surgery, any surgery to the legs or

pelvis, neurosurgery, or major trauma), your doctor may tell you to stop taking (in the case of elective surgery at least four weeks in advance) and not resume until two weeks after complete remobilisation. Another method of contraception should be used to avoid unintentional pregnancy. Your doctor may prescribe other treatment (e.g. treatment for blood clots) if Leven ED has not been discontinued in advance.

Other risk factors for blood clotting include temporary immobilisation including air travel of greater than 4 hours, particularly in women with other risk factors. Consult your doctor if you plan to air travel for greater than 4 hours. Consult your doctor if you develop high blood pressure while taking Leven ED – you may be told to stop taking it.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you vomit within 3 to 4 hours, or have severe diarrhoea after taking a beige active tablet, the active ingredients may not have been completely absorbed. This is like missing a tablet. Follow the advice for missed tablets.

If you have unexpected bleeding and it continues, becomes heavy, or occurs again, tell your doctor. When taking this Pill for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary products, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill, usually after about 3 months.

If you have missed a period, but you have taken all your tablets, it is unlikely that you are pregnant, as long as:

- you have taken the beige active tablets at the right time
- you have not been taking a medicine(s) that may interfere with your Pill
- you have not vomited or had severe diarrhoea during this cycle.

If this is so, continue to take Leven ED as usual. If you have any concerns consult your doctor or pharmacist.

If you miss your period twice in a row, you may be pregnant, even if you have taken the Pill correctly. Stop taking Leven ED and seek advice from your doctor. You must use a non-hormonal method of contraception (such as condoms or a diaphragm) until your doctor rules out pregnancy.

Leven ED will not protect you from HIV-AIDS or any other sexually transmitted infections (STIs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papillomavirus and syphilis.

To protect yourself from STIs, you will need to use additional barrier contraceptives (e.g. condoms).

Things you must not do

Do not take Leven ED to treat any other conditions, unless your doctor tells you to.

Do not give your medicine to anyone else.

Do not stop taking your medicine or change the dosage without checking with your doctor. You may become pregnant

if you are not using any other contraceptive and you stop taking Levlén ED, or do not take a tablet every day.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Levlén ED.

This Pill helps most women, but it may have unwanted side effects in some women.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

The following list includes the more common side effects of your Pill. These are usually mild and lessen with time.

If you notice any of the following side effects and they worry you, tell your doctor or pharmacist:

- acne
- nausea
- stomach pain
- changes in weight
- headache, including migraines
- mood changes, including depression
- breast tenderness or pain
- hair loss or hair growth.

The following list includes very serious but rare side effects. You may need urgent medical attention or hospitalisation.

If you experience any of the following, tell your doctor immediately, or go to the Accident and Emergency Department at your nearest hospital:

- pain in the chest, arm or below the breastbone
 - pain or discomfort that goes to your back
 - breathlessness and/or difficulty breathing
 - swelling, pain or tenderness of one leg
 - sudden weakness, numbness or bad 'pins and needles' of the face, arm or leg, especially on one side of the body
 - sudden trouble walking, dizziness, loss of balance or coordination
 - severe, sudden stomach pains
 - a fainting attack or you collapse
 - unusual headaches or migraines that are worse than usual
 - sudden problems with speaking, seeing or understanding what people are saying to you
- The side effects listed above are possible signs of a blood clot (thrombosis).
- jaundice (yellowing skin or yellowing eyes)
 - you cough up blood
 - breast lumps
 - unexplained vaginal bleeding.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

Blood clots and the Pill

Blood clots may block blood vessels in your body. This type of blood clot is also called thrombosis.

Blood clots sometimes occur in the deep veins of the legs. If a blood clot breaks away from the veins where it has formed, it may reach

and block the blood vessels of the lungs, causing pulmonary embolism.

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Blood clots are a rare occurrence and can develop whether or not you are taking the Pill. They can also happen during pregnancy. The risk of having blood clots is higher in Pill users than in non-users, but not as high as during pregnancy.

The risk of a blood clot is highest during the first year of taking the Pill for the first time, or after having a break from the Pill for 4 weeks or more.

If you notice possible signs of a blood clot, stop taking Levlén ED and consult your doctor immediately. To prevent pregnancy, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm).

If you are concerned about an increased risk of blood clots while on Levlén ED, speak to your doctor.

Cancer and the Pill

Breast cancer has been diagnosed slightly more often in women who take the Pill than in women of the same age who do not take the Pill.

This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after women stop taking the Pill.

It is not known whether the difference is caused by the Pill. It may be that these women were examined more often, so that the breast cancer was noticed earlier.

It is important that you check your breasts regularly and contact your doctor if you feel any lumps.

In rare cases benign liver tumours and, even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding.

Contact your doctor immediately if you have severe pain in your abdomen.

Cervical cancer has been reported to occur more often in women who have been taking the Pill for a long time. This finding may not be caused by the Pill, but may be related to sexual behaviour and other factors.

AFTER TAKING LEVLÉN ED

Storage

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store your tablets or any other medicine in the bathroom, near a sink, or on a window-sill. Do not leave medication in the car. Heat and damp can destroy some medicines.

Keep Levlén ED where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What Levlén ED looks like

Levlén ED active tablets are beige and round.

Levlén ED inactive tablets are white and round.

Levlén ED comes in a box containing 1 or 4 blister packs. Not all pack sizes may be marketed.

Each blister pack contains 21 beige active tablets and 7 white inactive tablets.

Ingredients

Each Levlén ED beige active tablet contains:

- Active ingredients:**
- 30 microgram of ethinylestradiol
 - 150 microgram of levonorgestrel

Inactive ingredients:

- calcium carbonate
- glycerol
- glycol montanate
- iron oxide yellow
- lactose monohydrate
- macrogol 6000
- magnesium stearate
- maize starch
- povidone
- purified talc
- sucrose
- titanium dioxide

Each white inactive tablet contains:

- calcium carbonate
- glycol montanate
- lactose monohydrate
- macrogol 6000
- magnesium stearate
- maize starch
- povidone
- purified talc
- sucrose

Tablets do not contain gluten. Tablets also do not contain tartrazine or any other azo dyes.

Supplier

Made in Germany for:

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Australian Registration Number

Levlén ED - AUST R 40193

Date of Preparation

March 2020

See TGA website (www.cbs.tga.gov.au) for latest Australian Consumer Medicine Information.

Missed a pill?

See the end of this leaflet.

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Summary of advice if you missed a beige active tablet more than 12 hours ago.

<p>Before missing your tablet, did you take beige active tablets for the previous 7 days?</p>	<p>No</p>	<p>Did you have sex in the 7 days before missing the tablet?</p>	<p>→</p> <p>No Take the tablet missed AND use extra barrier precaution for 7 days. If there are fewer than 7 beige active tablets left in the pack, finish the beige active tablets and go straight to the beige active tablets of the next pack. This means you skip the white inactive tablets.</p> <p>Yes See your Doctor or Pharmacist for advice</p>
	<p>Yes</p>	<p>Does your pack still have 7 beige active tablets in a row to follow?</p>	<p>→</p> <p>No Take the tablet you missed AND complete taking the beige active tablets. Skip the white inactive tablets. Start your next pack with beige active tablets.</p> <p>Yes Take the tablet you missed AND complete the pack as normal</p>

Progestogen-Only Pill (Mini-pill)

MICROLUT[®] (MY·crow·loot)

Contraceptive tablets for women

levonorgestrel

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Microlut. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Microlut against the benefits they expect it will have for you.

If you have any concerns, or are unsure about taking this medicine, ask your doctor or pharmacist for more advice.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT MICROLUT IS USED FOR

Microlut is an oral progestogen-only contraceptive, commonly known as the 'Mini-pill'.

Microlut is used to prevent pregnancy.

When taken correctly, it prevents you from becoming pregnant in several ways, including:

- changing the cervical mucus consistency, making it more difficult for the sperm to reach the egg

- changing the lining of the uterus, making it less suitable for implantation
- impairing mid-cycle functions, which may contribute to contraceptive action.

Like all oral contraceptives (OC), Microlut is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted infections.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE MICROLUT

When you must not take it

Do not take Microlut if you have an allergy to:

- levonorgestrel the active ingredient in Microlut
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Microlut if you have or have had a blood clot in:

- the blood vessels of the legs (deep vein thrombosis - DVT)
- the lungs (pulmonary embolism - PE)
- the heart (heart attack)
- the brain (stroke)
- other parts of the body.

Do not take Microlut if you are concerned about an increased risk of blood clots. Blood clots are rare.

Very occasionally blood clots may cause serious permanent disability, and may even be fatal.

You are more at risk of having a blood clot when you take the Mini-pill. However, the risk of having a blood clot when taking the Mini-pill is less than the risk of having a blood clot during pregnancy.

Do not take Microlut if you are concerned about an increased risk of blood clots because of age or smoking.

The risk of having a heart attack or stroke increases as you get older. It also increases if you smoke. You should stop smoking when taking the Mini-pill, especially if you are older than 35 years of age.

Do not take Microlut if you have, or have had:

- diabetes mellitus with blood vessel damage
- severe liver disease and your liver function has not returned to normal
- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- benign or malignant liver tumour
- unexplained vaginal bleeding.

Do not take this medicine if you are pregnant or think you might be pregnant.

Do not give this medicine to a child.

Microlut is not intended for use in females whose periods have not yet started.

Do not take this medicine after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- you smoke

- you have abdominal pain with infrequent and/ or irregular periods
- you have ever had an extra uterine/ectopic pregnancy (where an embryo has developed outside the womb) or an impairment in your fallopian tube function (e.g. caused by inflammation).
- you or anyone in your immediate family has had blood clots in the legs (DVT) or lungs (PE), a heart attack, a stroke, breast cancer or high cholesterol.

Tell your doctor if you have, or have had any of the following medical conditions:

- diabetes
- high blood pressure
- kidney or heart problems
- migraine
- asthma
- epilepsy
- depression

Ask your doctor to check if you:

- are overweight
- have high cholesterol or triglycerides
- have liver disease
- have gall bladder disease
- have a condition that occurred for the first time, or worsened during pregnancy or previous use of sex hormones (e.g. cholestatic jaundice and/or pruritis (itching))
- have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid exposure to the sun or ultraviolet radiation.

If any of the above conditions appear for the first time, recur or worsen while taking Microlut, you should contact your doctor.

Microlut contains lactose. If you have an intolerance to some

sugars, contact your doctor before you start taking Microlut.

If you have not told your doctor about any of the above, tell him/her before you start taking Microlut.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Microlut may interfere with each other. These include:

- medicines used to treat tuberculosis such as rifampicin, rifabutin
- a class of antibiotics known as macrolides, such as clarithromycin, erythromycin
- medicines used to treat fungal infections, such as ketoconazole, griseofulvin
- medicines used to treat HIV, such as ritonavir, nevirapine
- some medicines used to treat Hepatitis C Virus (HCV), such as boceprevir, telaprevir
- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- antibiotics (e.g. penicillins, nitrofurantoin, tetracycline)
- cyclosporin, an immunosuppressant medicine
- some medicines used to treat high blood pressure, chest pain or irregular

- heartbeats such as diltiazem, verapamil
- herbal medicines containing St John's Wort
 - grapefruit juice.

These medicines may be affected by Microlut, or may affect how well it works. Your doctor may need to alter the dose of your medicine, or prescribe a different medicine.

You may need to use additional barrier methods of contraception (such as condoms or a diaphragm) while you are taking any of these medicines and for some time after stopping them. Your doctor will be able to advise you on how long you will need to use additional contraceptive methods. Your doctor and pharmacist have more information on medicines that you need to be careful with or avoid while taking this medicine.

HOW TO TAKE MICROLUT

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, on the pharmacist label or in this leaflet, ask your doctor or pharmacist for help.

How to take it

Take one tablet daily at the same time every day. You must take Microlut every day regardless of how often you have sex. This will also help you remember when to take it.

An interval of exactly 24 hours should be maintained between tablets. This interval must not be exceeded by more than 3 hours.

Even if one tablet is taken late (i.e. more than 3 hours later than when it should have been taken) or if one tablet is missed altogether, protection against pregnancy may be impaired.

Swallow the tablet whole with water. It does not matter if you take it before or after food.

Each blister pack is marked with the day of the week. **Take your first tablet from the blister pack corresponding to the day of the week.**

Follow the direction of the arrows on the blister pack until all the tablets have been taken. Each blister pack is marked with the day of the week.

Tablets must be taken for 28 consecutive days. There is no break between packs. This means that when the first pack is finished the next should be started without interruption.

If you do not understand the instructions on the blister pack, ask your doctor or pharmacist for help.

Always start a new blister pack on the same day of the week as your previous pack.

Taking Microlut for the first time

If you are starting Microlut after a natural cycle, and you have not used a hormonal contraceptive in the past month, start on the first day of your period, i.e. on the first day of your menstrual bleeding.

Your doctor will advise you when to start if you:

- are taking Microlut after having a baby
- are breast-feeding
- have had a miscarriage or an abortion.

Changing from another contraceptive

Changing from a combined oral contraceptive:

Start taking Microlut on the day after taking the last active tablet in your previous pill pack. Do not take the inactive (sugar) tablets of your previous pack.

If you are not sure which were active/inactive tablets in your previous pill pack, ask your doctor or pharmacist.

Your previous pill pack may have different colour tablets to those of Microlut.

Changing from a progestogen-only pill ('minipill'):

Stop taking the previous Mini-pill on any day and start taking Microlut at the same time the next day, with out any break between Mini-pills.

Changing from a progesterone only injection or implant:

Start taking Microlut when your next injection is due, or on the day that your implant is removed.

You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.

Stopping Microlut

You can stop taking Microlut at any time. If you are considering becoming pregnant, it is recommended that you begin taking a vitamin supplement containing folic acid. It is best that you start taking folic acid tablets before you stop taking Microlut and not stop until your doctor advises this. Seek advice from your doctor or pharmacist about suitable supplements. It is both safe and recommended that you take folic acid during pregnancy.

Additional contraceptive precautions

When additional contraceptive precautions are required you should either abstain from sex, or use a barrier method of contraception, a cap (or diaphragm) plus spermicide, or a condom. Rhythm methods are not advised as Microlut disrupts the cyclical changes associated with the natural menstrual cycle e.g. changes in temperature and cervical mucus.

If you forget to take it

If you miss a tablet, take the missed tablet as soon as you remember, even if this means taking two tablets at the same time. Then continue to take your tablets at the usual time. In addition, you should also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the next 7 days.

If you have had sexual intercourse in the week before, taking your tablet(s) late or missed a tablet(s), there is a high possibility of becoming pregnant. **Seek advice from your doctor or pharmacist about what to do.**

Please refer to the table at the end of this leaflet "Summary of

advice when late taking or missing a Mini-pill".

Ask your doctor or pharmacist to answer any questions you may have.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26) for advice, or go to the Accident and Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much Microlut. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

WHILE YOU ARE TAKING MICROLUT

Things you must do

Tell any doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Have regular check-ups with your doctor.

When you are taking Microlut, your doctor will tell you to return for regular check ups, including getting a Pap smear test. Your doctor will advise how often you need a Pap smear test. A Pap smear test can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cancer.

If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking Microlut.

Stop taking Microlut and see your doctor immediately if you notice possible signs of thrombosis. These include:

- an unusual cough
- severe pain or heaviness in the chest
- breathlessness
- any unusual, severe, or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- slurring or speech disability
- sudden changes to your hearing, sense of smell, or taste
- dizziness or fainting
- weakness or numbness in any part of your body
- severe pain in your abdomen
- severe pain, swelling or discolouration in either of your legs.

If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are taking Microlut. The risk of having DVT is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg(s) in plaster/splints). In women who take the Mini-pill, the risk may be higher.

Your doctor may tell you to stop taking the Mini-pill several weeks before surgery, or at the time of immobilisation, and when you can start taking the Mini-pill again. If you notice possible signs of a thrombosis, stop taking the Mini-pill and consult your doctor immediately.

Consult your doctor if you develop high blood pressure while taking Microlut – you may be told to stop taking it.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you vomit within 3–4 hours or have severe diarrhoea after taking a tablet, the active ingredients may not have been completely absorbed. This is like missing a tablet. Follow the advice for missed tablets.

If you have unexpected bleeding and it continues, becomes heavy, or occurs again, tell your doctor.

When taking these tablets for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Mini-pill, usually after about 3 months.

If you have missed a period, but you have taken all your tablets, it is unlikely that you are pregnant as long as:

- you have taken the tablets at the right time
- you have not been taking a medicine(s) that may interfere with your Mini-pill
- you have not vomited or had severe diarrhoea during this cycle.

If this is so, continue to take Microlut as usual. If you have any concerns consult your doctor or pharmacist.

If you miss your period twice in a row, you may be pregnant

even if you have taken Microlut correctly. Stop taking Microlut and seek advice from your doctor. You must use a non-hormonal method of contraception (such as condoms, or a diaphragm) until your doctor rules out pregnancy.

Microlut will not protect you from HIV-AIDS or any other sexually transmitted infection (STIs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papillomavirus and syphilis.

To protect yourself from STIs, you will need to use additional barrier contraceptives (e.g. condoms).

Things you must not do
Do not take Microlut to treat any other conditions, unless your doctor tells you to.

Do not give your medicine to anyone else.

Do not stop taking your medicine or change the dosage without checking with your doctor.

You may become pregnant if you are not using any other contraceptive and you stop taking Microlut, or do not take a tablet every day.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Microlut.

This medicine helps most women, but it may have unwanted side effects in some women.

All medicines can have side effects. Sometimes they are serious, most of the time they are

not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor or pharmacist if you feel unwell.

Other side effects not listed on the following pages may also occur in some people.

The following list includes the more common side effects of your medicine. These are usually mild and lessen with time.

If you notice any of the following side effects and they worry you, tell your doctor or pharmacist:

- nausea, vomiting
- stomach pain together with bleeding irregularities including more frequent, less frequent or no bleeding
- headache, including migraines
- dizziness
- mood changes, including depression
- breast tenderness or pain.

The following list includes very serious but rare side effects. You may need urgent medical attention or hospitalisation.

If you experience any of the following, tell your doctor immediately, or go to the Emergency Department at your nearest hospital:

- pain in the chest, arm or below the breastbone

- discomfort radiating to the back
 - breathlessness and/or difficulty breathing
 - swelling, pain or tenderness in one leg
 - sudden weakness, numbness or bad 'pins and needles' of the face, arm or leg, especially on one side of the body
 - sudden trouble walking, dizziness, loss of balance or coordination
 - severe, sudden stomach pains
 - a fainting attack, or you collapse
 - unusual headaches or migraines that are worse than usual
 - sudden problems with speech, understanding or eyesight
- The side effects listed above are possible signs of a blood clot (thrombosis).
- jaundice (yellowing skin or yellowing eyes)
 - you cough up blood
 - breast lumps
 - unexplained lower abdominal pain, including loss of periods or heavy bleeding. In rare cases pregnancies may occur during use of the mini-pill. These pregnancies are more likely to be extrauterine/ectopic (where the embryo grows outside of the womb)
 - unexplained vaginal bleeding.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

Thrombosis and the Mini-pill

Thrombosis is the formation of a blood clot that may block a blood vessel.

Thrombosis sometimes occurs in the deep veins of the legs (DVT). If a blood clot breaks away from the veins where it has formed, it may reach and block the arteries of the lungs, causing pulmonary embolism (PE).

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Blood clots are a rare occurrence and can develop whether or not you are taking the Mini-pill. They can also happen during pregnancy. The risk of having blood clots is higher in Mini-pill users than in non-users, but not as high as during pregnancy.

The risk of a blood clot is highest during the first year of taking the Mini-pill for the first time, or after having a break from the Mini-pill for 4 weeks or more.

If you notice possible signs of a blood clot, stop taking Microlut and consult your doctor immediately.

If you are concerned about an increased risk of blood clots while on Microlut, speak to your doctor.

Cancer and the Mini-pill

Breast cancer has been diagnosed slightly more often in women who use oral contraception than in women of the same age who do not. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after women stop taking the Mini-pill.

It is not known whether the difference is caused by the Mini-pill. It may be that these women were examined more often, so that the breast cancer was noticed earlier.

It is important that you check your breasts regularly and contact your doctor if you feel any lump.

In rare cases benign liver tumours and, even more rarely, malignant liver tumours have been reported in users of the Mini-pill. These tumours may lead to internal bleeding.

Contact your doctor immediately if you have severe pain in your abdomen.

Cervical cancer has been reported to occur more often in women who have been taking the Mini-pill for a long time. This finding may not be caused by the Mini-pill, but may be related to sexual behaviour and other factors.

AFTER TAKING MICROLUT

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store your tablets or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave medication in the car. Heat and damp can destroy some medicines.

Keep Microlut where children cannot reach it. A locked cupboard at least one-and-a-half metres above

the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Microlut comes in a box containing 1 or 4 blister packs. Each blister pack contains 28 white active tablets. Not all pack sizes may be marketed.

Ingredients

Active ingredients:

- Microlut – 30 microgram of levonorgestrel per tablet

Each tablet also contains:

- calcium carbonate
- glycol montanate
- lactose monohydrate
- macrogol 6000
- magnesium stearate
- maize starch
- povidone
- purified talc
- sucrose

Tablets do not contain gluten. Tablets also do not contain tartrazine or any other azo dyes.

Supplier

Made in Germany for:
Bayer Australia Ltd

ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Australian Registration Number

Microlut - AUST R 10696

Date of Preparation

February 2017

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

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Summary of advice when late taking or missing a Mini-pill

<p>If it has been more than 27 hours since your last tablet was taken or you have missed a tablet, then:</p>	<ul style="list-style-type: none"> • Take the tablet you missed even if this means taking two at the same time. Use barrier contraception for the next 7 days. • Continue taking tablets at usual time. 	<ul style="list-style-type: none"> • If you had sex in the 7 days prior to taking your late tablet or missed tablet, the risk of pregnancy is increased. • Contact your doctor or pharmacist for advice
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Appendix U

Baseline Survey – Chapter 6

Consent

Q1 Do you understand everything in the participant information sheet and consent to participate in this study?

- Yes
- No

Inclusion Criteria

Q1 Do you currently use/take the oral contraceptive pill (the 'pill')?

- Yes
- No

Q2 Do you use/take the oral contraceptive pill mainly for contraception/prevention of pregnancy

- Yes
- No

Q3 How do you identify?

- Female
- Male
- Another gender, please specify _____

Q4 What is your age? Please write in numbers (e.g. 32)

Demographics

Q1 Please create a unique participant ID so that all your responses can be linked. This will also ensure anonymity of your data.

Please use the **FIRST THREE LETTERS** of your mother's maiden name and the **LAST THREE NUMBERS** of your mobile number (e.g. MAC498)

Q2 Please provide your email address so you can receive the three follow-up surveys

Q3 What type of oral contraceptive pill do you currently use?

- Combination pill - These are used in one-month cycles and each active pill gives you a dose of hormone. During the last week of the cycle, you take inactive pills and have your period.
- Combination pill - Extended Cycle - These are typically used in 13-week cycles. You take active pills for 12 weeks, and during the last week of the cycle, you take inactive pills and have your period. As a result, you have your period only three to four times per year.
- Progestin-only pill/Mini pill - With these progestin-only pills, all pills in the cycle are active. There are no inactive pills, so you may or may not have a period while taking progestin-only pills.

Q4 How long have you been using the oral contraceptive pill?

- Number of years or, _____
- Number of months _____

Q5 Are you sexually active?

- Yes
- No
- Don't want to say

Q6 How did you select this method of contraception? (oral contraceptive pill)

- Advised by general physician (doctor)
- Advised by gynaecologist
- Own preference (but received prescription from doctor)
- Do not remember
- Other, please specify _____

Q7 Have you ever been pregnant?

- Yes
- No
- Don't want to say

Q8 Have you ever used emergency contraception (e.g. the morning after pill)?

- Yes
- No
- Don't want to say

Q9 How many children do you have? Please write as a number (e.g. 0)

Q10 What is the highest level of education you have completed? If currently enrolled, highest degree received.

- No schooling completed
- Primary school
- Secondary school, high school, diploma or equivalent (e.g. WACE)
- Some university, no degree
- Bachelor's Degree (e.g. BA, BS)
- Postgraduate Degree (e.g. Masters)
- Professional degree (e.g. MD, DDS, DVM)
- Doctorate (e.g. PhD, EdD)
- Trade/technical/vocational training

Q11 How would you predominantly describe yourself?

- Indigenous Australian or Torres Strait Islander
- Caucasian/European Australian
- Asian/Asian Australian
- Middle Eastern
- African American
- Hispanic or Latinx
- European
- Other _____

Q6. How much is experiencing these cues likely to make you take your oral contraceptive pill?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer



Social Cues

Q7. Are there any social situations which trigger you to take your oral contraceptive pill? (e.g., hanging out with certain friends)

- Yes
- No

Q8. How often are you in these social situations?

	Never	A few times a year	Monthly	A few times a month	Every week	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q9. How much is being in these situations likely to make you take your oral contraceptive pill?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer



Internal Cues

Q10. Are there any internal drives which trigger you to take your oral contraceptive pill? (e.g., feeling sleepy, hungry, thirsty)

- Yes
- No

Q11. How often do you feel these internal cues?

	Never	A few times a year	Monthly	A few times a month	Weekly	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q12. How much is feeling these cues likely to make you take your oral contraceptive pill?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer

Emotional Cues

Q13. Are there any emotional drives which trigger you to take your oral contraceptive pill? (e.g., feeling sad or happy)

- Yes
- No

Q14. How often do you feel these emotional cues?

	Never	A few times a year	Monthly	A few times a month	Weekly	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q15. How much is feeling these cues likely to make you take your oral contraceptive pill?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer

Medication Adherence Report Scale (MARS-5)

Q1 Please rate how much each of the below statements describes your oral contraceptive pill use in the previous month

I have no need to think about doing.	<input type="radio"/>							
That's typically 'me'.	<input type="radio"/>							
I have been doing for a long time.	<input type="radio"/>							

Cues to Action Scale

Physical Cues

Q1. Are there any physical things in the environment which trigger you to take your oral contraceptive pill? (e.g. a particular shop, advertisement, alarm)? *Note: If answered 'no' was taken to next type of cue*

- Yes
- No

Q2. How often do you see these physical cues?

	Never	A few times a year	Monthly	A few times a month	Every week	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>							

Q3. How much is seeing these cues likely to make you take your oral contraceptive pill?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer

Sensory Cues

Q4. Are there any sensory things in the environment which trigger you to take your oral contraceptive pill? (e.g., a certain smell)

- Yes
- No

Q5. How often do you experience these sensory cues?

	Never	A few times a year	Monthly	A few times a month	Every week	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q6. How much is experiencing these cues likely to make you take your oral contraceptive pill?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer

Social Cues

Q7. Are there any social situations which trigger you to take your oral contraceptive pill? (e.g., hanging out with certain friends)

- Yes
- No

Q8. How often are you in these social situations?

	Never	A few times a year	Monthly	A few times a month	Every week	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q9. How much is being in these situations likely to make you take your oral contraceptive pill?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer

Internal Cues

Q10. Are there any internal drives which trigger you to take your oral contraceptive pill? (e.g., feeling sleepy, hungry, thirsty)

- Yes
- No

Q11. How often do you feel these internal cues?

	Never	A few times a year	Monthly	A few times a month	Weekly	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q12. How much is feeling these cues likely to make you take your oral contraceptive pill?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer

Emotional Cues

Q13. Are there any emotional drives which trigger you to take your oral contraceptive pill? (e.g., feeling sad or happy)

- Yes
- No

Q14. How often do you feel these emotional cues?

	Never	A few times a year	Monthly	A few times a month	Weekly	A few times a week	Every day	A few times a day
Please select	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q15. How much is feeling these cues likely to make you take your oral contraceptive pill?

Not at all likely (0) - Every time (6)

0 1 2 3 4 5 6

Please drag the slider to the correct answer

