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Results of a Randomized Controlled Trial to promote Physical Activity Behaviours in Mothers with Young Children

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Introduction

Physical inactivity is identified as a modifiable risk factor that is linked to chronic disease in all ages across the globe (World Health Organisation, 2010, World Health Organisation, 2008). It is estimated to cause 6-10% of the major non-communicable diseases of coronary heart disease, type 2 Diabetes and breast and colon cancer (Lee et al., 2012).

Worldwide, women have lower rates of physical activity compared to men; Australia 51.4% women vs. 65.8% men; Canada 54.8% vs. 64.4%; USA 57.6% vs. 67.2%; New Zealand 52.2% vs. 74% (Bauman et al., 2009). Furthermore, physical activity declines during pregnancy and post-partum period (Liu et al., 2011, Evenson, 2011, Borodulin et al., 2009) and is linked to the demands of multiple role expectations (Ransdell et al., 2004) (e.g. caring for children) and changes in life events leading to lack of time, fatigue, lack of motivation and financial constraints (Bell and Lee, 2005, Borodulin et al., 2008, Symons Downs and Hausenblas, 2004, Brown et al., 2001). Lack of physical activity among pregnant and post-partum women is associated with negative impact on the health of the mother and the child, including gestational diabetes, mental health, musculoskeletal issues and weight gain (Tobias et al., 2011, Pivarnik et al., 2006).

In 2007-08, 45% of Australian women of childbearing age (25 and 34 years) were overweight or obese and 75% were classified as sedentary or had a low activity level (Australian Bureau of Statistics, 2009). Women's propensity to become overweight and obese during the childbearing years is linked to high body mass index (BMI) prior to pregnancy, excessive gestational weight gain, failure to lose excessive weight in the postpartum period within a 12 month timeframe and inter-pregnancy weight gain (Keitt et al., 2008, Ryan, 2007, Davis et al., 2010, Callaway et al., 2006). Obese women of childbearing age are at greater risk of short-term adverse health consequences during pregnancy and postpartum period (Ramachenderan et al.,

2008, Ruager-Martin et al., 2010) and long-term weight retention (Linne et al., 2004, Rooney et al., 2005). Evidence also demonstrates that individuals who are overweight or obese and inactive face the highest risk of morbidity or mortality (Lee et al., 2009, Siega-Riz et al., 2009, Gore et al., 2003). Hence, improving the physical activity levels of mothers with young children is important from a public health perspective.

Systematic literature reviews report on a number of interventions for pregnant women and mothers with children (Amorim et al., 2007, Birdsall et al., 2009, Dodd et al., 2010, Hartman et al., 2010, Keller et al., 2008, Kuhlmann et al., 2008, Lombard et al., 2009b, Ronnberg, 2010, Skouteris et al., 2010). However, a review of the literature demonstrates that there are limited community based randomized controlled trials addressing diet and physical activity specifically designed for mothers with young children (O'Toole et al., 2003, Craigie et al., 2011, Fahrenwald and Sharma, 2002, Fjeldsoe et al., 2010, Liu et al., 2009, Lombard et al., 2009a, Miller et al., 2002). Further, some of these interventions only include women with Body Mass Index <25 (O'Toole et al., 2003) or those who are ready to be more physically active (Fjeldsoe et al., 2010). Hence, there is a urgent need for further research on tailored dietary and physical activity interventions for mothers with young children (Amorim et al., 2007, Birdsall et al., 2009, Dodd et al., 2010, Hartman et al., 2010, Keller et al., 2008, Kuhlmann et al., 2008, Ronnberg, 2010, Skouteris et al., 2010, Streuling et al., 2010, Thangaratinam and Jolly, 2010).

Becoming a mother is a redefining time for health, as health behaviours are often altered to accommodate the needs of motherhood (Walker and Wilging, 2000). It has been reported that after having babies women are motivated to participate in programs to reduce their weight (Bastion et al., 2011) It therefore may be an opportunistic time to commence health promotion activities to improve women's immediate and long-term health (Walker and Wilging, 2000), which in turn will impact on the health of the children.

Recent evidence also reports that as little as one hour of moderate intensity physical activity per week can significantly reduce women's risk of cardiovascular diseases, diabetes, breast cancer and endometrial cancer (U.S. Department of Health and Human Services (USDHHS), 1996, Brown et al., 2007). Accordingly, this study aimed to increase the levels of physical activity of mothers via a home-based intervention conducted in playgroups (Reminder on Food, Relaxation, Exercise and

Support for Health: REFRESH). This paper presents changes in physical activity and muscle strength exercise from baseline to post-intervention.

Methods

Trial Design and Intervention Components

The study was a two-arm (intervention and control group) randomized controlled trial (RCT). The intervention design was based on a pilot project that produced encouraging results with respect to adherence and behaviour change (Jones et al., 2010). The intervention group received a six-month physical activity intervention. The physical activity component was based on the 2007 American College of Sports Medicine (ACSM) (Haskell et al., 2007) and American Heart Association (AHA) physical activity guidelines (Pollock et al., 2000). Dietary information was also provided and outcome data collected but due to the complexity of the analysis this will be presented separately.

The behaviour change theories and techniques used to assist in the development of the intervention included the Social Cognitive Theory (Glanz et al., 2008), Transtheoretical Model (Prochaska and Diclemente, 1983) and motivational interviewing (Rollnick and Miller, 1995). The 6-month home-based intervention provided information and advice on the recommended levels of physical activity (30 minutes of moderate physical activity on five or all days of the week) and appropriate muscle strength and flexibility exercises. The resources comprised a comprehensive booklet, muscle strength and flexibility exercise chart, physical activity diary and pedometer. There were four electronic (email) or hard copy (mail) newsletters containing health information and advice and 18 key short message service (SMS) on suitable health behaviours. The home based program was reinforced by five 30 minute monthly face to face workshops and skill development sessions delivered by 12 trained staff in the playgroup setting.

The resources/activities provided information on the health benefits of physical activity; encouraged skill development to support the integration of physical activity into daily living and goal setting; promoted discussion on the barriers and potential solutions to being active; supported increased self-efficacy and social support for physical activity; and provided skills to prevent relapse. Full details of the intervention are provided elsewhere (Monteiro et al., 2011). The control group did not receive the intervention, and the only contact with the project occurred when they completed the questionnaires.

Recruitment and Randomization

Playgroup Western Australia (Playgroup WA Inc.) is the governing body for playgroups in the State. Playgroups provide an informal local setting for women and children to come together to socialise. Women attend the playgroup with their pre-school child (usually 0-4years) on a set day every week. The playgroups are run by volunteer parents and are held in a variety of venues such as church halls, community centres and child health centres. Women submit applications to join the local playgroup. Each playgroup may have up to 10 sessions per week. The number of attendees at each session is usually restricted to about 10-12 families.

Playgroup WA staff contacted playgroups registered in the Perth metropolitan area and obtained consent for the project staff to visit the playgroups. The suburbs (neighborhoods) (n=60) were matched for low and medium Socio-Economic Indexes for Area (SEIFA) values and then randomly assigned to the intervention (n=30) or control (n=30) group (Australian Bureau of Statistics, 1998). (SEIFA values ranged from 866-1151)

To be eligible for participation in the study, participants were required to be: women aged 18 years and above; registered with Playgroup WA. Inc.; have at least one child aged 0-5 years; considered "healthy" to the extent that participation in a low-stress physical activity program would not place them at risk; and no special diet. The intervention group participants completed the Physical Activity Readiness Questionnaire (PARQ) (Thomas et al., 1992) and provided a medical certificate if deemed necessary before commencing the program. Of the 1140 participants who were recruited, 716 participants consented to the study and were randomized to either the intervention (n=394) or control (n=322) group (Figure 1).

Ethics approval was obtained from the Curtin University Human Research Ethics Committee (approval number HR 183/2008). Trial Registration: Australian and New Zealand Clinical Trials Registry ACTRN12609000735257. Further detailed information is published in the protocol article (Monteiro et al., 2011).

Physical Activity Measurements

Physical activity was assessed using the International Physical Activity Questionnaire-Short Version (IPAQ-SV) (Craig et al., 2003a). This instrument has been accepted as an appropriate physical activity measurement tool in many settings and measures physical activity in 'minutes/day' and 'days/week' (Craig et al., 2003b). Walking, moderate physical activity and vigorous physical activity were measured independently. Moderate intensity activities were defined as those that made one breathe somewhat harder than normal and increased the heart rate. Vigorous intensity activities were defined as activities that required hard physical effort and made one breathe much harder than normal ('huff and puff'). Muscle strength exercise questions were based on the American Heart Association (AHA) guidelines (Pollock et al., 2000) and measured in 'days' (Morrow et al., 2011).

Statistical Analysis

Descriptive statistics are reported as the mean (\pm SD) for continuous data and percentages for categorical data. The effects of the intervention on continuous outcome measures were assessed using analysis of variance (ANOVA). All data was analysed including and excluding mothers who were pregnant, breastfeeding and postpartum (up to 12 months). The statistical analyses were performed using Statistical Package for Social Sciences (SPSS, Version 18) and p-values < 0.05 were considered statistically significant.

The baseline data for the 716 participants, were used to determine the median (or 50th percentile) for vigorous, moderate and total physical activity, all expressed as minutes per week. These medians were subsequently used to categorise each of the physical activity variables into two groups, above and below the median. A McNemar test was used to assess the change in the status of the correlated data from above or below the median at baseline to above or below the median post-intervention for each of the physical activity variables comparing the two groups.

A change in the positive direction was due to a change in the number of participants who improved in physical activity as a result of a change from below the median at baseline to a change above the median post-intervention. A change in the negative direction indicating reduction in physical activity and was the result of a change from above the median at baseline to a change below the median post-intervention. Net change for each of the physical activity variables and for each of the groups was calculated as a change in the positive direction subtracting the change in the negative direction, expressed as percentage of subjects of the total sample.

Results

A total of 521 participants (73%) completed the study. At six-months, the overall attrition was 27.3% with 16% (n=50) being in the control group and 37% (n=145) in the intervention group.

(Insert Figure 1)

The mothers were generally above 25 years of age, with the distribution relatively similar between 25-35 and 35 years and over. The majority of women were classified as a healthy weight (60.8%), 30.2% were classified as overweight and 9% as obese. The majority of women (61.5%) were university educated. (See Table 1).. Of those participants who did not complete the 6-month intervention, 29.7% were pregnant, postpartum or breastfeeding compared to 38% of mothers who completed the intervention ($p=0.040$). Participants who withdrew from the study were slightly younger (about 9 months) ($p=0.044$) and had a lower waist circumference (2.8cm) ($p=0.025$) compared to women who completed the study. Apart from these minor differences, those withdrawing before the completion of the study were comparable to those who completed the study. Mothers who withdrew were not significantly different in parity, participation in strength muscle group exercises, BMI and waist to hip ratio ($p>0.05$).

(Insert Table 1)

The intervention had a significant effect on the weekly mean time for vigorous ($p=0.008$), moderate ($p=0.023$) and total physical activity ($p=0.001$) but did not have an effect on muscle strength exercises ($p>0.05$) when compared to the control group.

(Insert Table 2)

The intervention group increased their weekly mean time for vigorous physical activity by 24 minutes, moderate physical activity by 23 minutes and total physical activity by 72 minutes. Excluding mothers who were pregnant, postpartum and breastfeeding, slightly larger differences were observed between groups. The intervention and control groups were not significant in the time spent on muscle strength exercises, both for all mothers ($p>0.85$) and excluding mothers who were pregnant, postpartum and breastfeeding ($p>0.64$).

The net change for each of the physical activity variables (moderate and vigorous) and for each of the groups is presented in Figure 2. It is calculated as a change in the positive direction subtracting the change in the negative direction, expressed as percentage of subjects of the total sample. Net change is calculated as the difference between the percentage of participants who improved, by moving to a higher category, and the percentage of subjects who were classified in a lower category of the outcome variable. The intervention group consistently showed a net positive change in the physical activity variables (moderate, vigorous, moderate + vigorous), whereas the control group consistently showed a net negative change.

(Insert Figure 2)

The percentage of participants who improved in each of the physical activity variables under the intervention were significantly greater than the participants who declined ($p < 0.05$). In the control group, however, the percentage of participants who improved in each of the physical activity variables were not significantly different from the participants who declined ($p > 0.05$). Similar results were observed when the data for all mothers were analysed and when data for mothers who were pregnant, postpartum and breastfeeding were excluded from the analysis.

DISCUSSION

Sample Characteristics

A review of the literature demonstrates that the REFRESH physical activity study may be the largest RCT (baseline sample size of 716) specifically targeting mothers with young children (aged between 0 to 5 years) (Craigie et al., 2011, Fahrenwald and Sharma, 2002, Fjeldsoe et al., 2010, Lombard et al., 2009a, Miller et al., 2002, O'Toole et al., 2003, Cramp and Brawley, 2006, Gaston and Prapavessis, 2009, Hausenblas et al., 2008, Huang et al., 2011, Jackson et al., 2011, Krummel et al., 2010, Polley et al., 2002, Thompson et al., 2008), except for the WIC studies which does not indicate if all women included had at least one child (Fahrenwald and Sharma, 2002, Krummel et al., 2010).

There has been limited community based intervention physical activity research programs aimed at reaching and retaining mothers of young children (Craigie et al., 2011, Fahrenwald and Sharma, 2002, Fjeldsoe et al., 2010, Lombard et al., 2009a, Miller et al., 2002, O'Toole et al., 2003). Such interventions may be particularly challenging due to the multiple role expectations placed on women during the childbearing years (Ransdell et al., 2004), the competing priorities and lifestyle

challenges that often lead to fatigue, restrictions on time and decreased motivation (Bell and Lee, 2005, Borodulin et al., 2008, Symons Downs and Hausenblas, 2004, Brown et al., 2001). In addition, the financial costs of raising children can reduce available funds, thereby prohibiting mothers from joining physical activity programs that charge.

This program used the playgroup setting to reach the mothers' of young children to provide them with resources to support an increase in their levels of physical activity. The home-based support materials comprised an information booklet, exercise chart, pedometer, SMS messaging and newsletter, enabling the women to work around their family demands. However, the program was supplemented by five short face-to-face sessions that reinforced the home-based program, providing an opportunity to clarify information and to interact in a supportive environment.

Considering the many competing demands of parenting, the number of mothers completing this six-month intervention was very encouraging, with an overall retention rate of 73% (intervention 63%; control 84%). The attrition rate in the control group (16%) was lower when compared to studies with similar populations including Fjeldsoe et al. (25%) (Fjeldsoe et al., 2010), Miller et al. (17%) (Miller et al., 2002) and Craigie et al. (39%) (Craigie et al., 2011).

It is also encouraging that the characteristics of those women who dropped out of the program were similar to completers (parity, participation in strength muscle group exercises, BMI and waist to hip ratio ($p>0.05$)), thereby increasing the relevance of the findings overall to this target group.

Physical Activity

The main objective of this intervention was to increase the physical activity levels of these mothers. Once again the results were encouraging with the intervention participants showing significant improvements in mean minutes per week of moderate ($p=0.023$), vigorous ($p=0.008$) and total physical activity ($p=0.001$) when compared to the control group. These REFRESH study results are difficult to compare to previous research due to the differences in reporting techniques (example, minutes per day (Craigie et al., 2011), MET minutes per week (Lombard et al., 2009a), hard bouts minutes per week (Ostbye et al., 2009)). However, this study reported more encouraging results than those reported by the Active Mothers Postpartum (AMP) study (Ostbye et al., 2008, Ostbye et al., 2009), and HeLP study

(Lombard et al., 2009a). The AMP and HeLP studies were predominantly face-to-face structured physical activity class interventions, which perhaps could have been better tailored to the target groups needs. The REFRESH results were similar to the Moms on the Move (MOM) study ($p < 0.05$) which was a predominantly telephone based intervention providing women the flexibility of being active at times convenient to them (Fahrenwald et al., 2004). The results in this study are also very positive, due to the program being primarily a home-based intervention supported by a face-to-face component, making replication realisable (Noar et al., 2007).

In addition, when mothers who were pregnant, postpartum and breastfeeding were excluded from the analysis slightly larger differences in mean physical activity times were observed between the control and intervention groups. This is to be expected and highlights the need for consideration of the physiological demands of these conditions on women when designing interventions (Hartman et al., 2010, Dewey and Lovelady, 1993, Morrow et al., 2011). Specific programs may be required for these particular target groups.

Muscle strength

The number of days that participants completed muscle strength exercises did not increase during the 6-month intervention. This is not unexpected, as it was a lesser component of the intervention, with the focus being on aerobic activity. Interestingly, a review of the literature, indicated that this may be the first program that attempted to incorporate strength exercises into an intervention for this target group (Amorim et al., 2007, Birdsall et al., 2009, Dodd et al., 2010, Hartman et al., 2010, Keller et al., 2008, Kuhlmann et al., 2008, Ronnberg, 2010, Skouteris et al., 2010, Streuling et al., 2010, Thangaratinam and Jolly, 2010). The Australian national physical activity guidelines do not include muscle strength exercise guidelines (Egger et al., 1999) and for this reason, this type of activity may not be perceived as important for health benefits. This warrants further investigation and potentially more of a focus when designing interventions with the target group.

Setting

This study is one of a few interventions aimed at improving the physical activity of mothers with young children, which has been previously identified as a hard to reach group (Hartman et al., 2010). The intervention indicates that playgroups provide a valuable and viable setting to recruit, engage and retain mothers of young children in

programs that support the adoption of health enhancing behaviours (Jones et al., 2010).

Limitations

This program was restricted to six-month duration, although this kind of timeframe should be adequate to reflect behaviour change (Keller et al., 2008, Kuhlmann et al., 2008). Similar to other interventions, self-selection bias can be an issue, as shown by the high number of university educated participants. However, this was minimised through the randomising of participants to the control and intervention groups. The collection of data on the age of children, length of time since birth and duration of breastfeeding would have provided greater insight into the target group but on consideration of subject burden these variables were collected. Finally, data were collected via self-complete questionnaires, which may lead to some over reporting of physical activity. The literature, however, suggests that self-report data has been found to be adequate for monitoring changes over time in such interventions, especially when a control group is also used (Eakin et al., 2009, Dhaliwal et al., 2010, Morey et al., 2009).

Conclusions

This relatively minimal intervention program was able to demonstrate modest but statistically significant improvements in physical activity behaviour (moderate, vigorous and total physical activity) in a hard to reach target group via the playgroup setting. These changes in behaviour, if maintained over a longer period are likely to reduce the impact of several chronic conditions such as Type 2 diabetes, cardiovascular disease and some cancers. In addition, the improved health behaviours of mothers is likely to also have a positive impact on their partners and children. It appears that this is one of the few effective physical activity interventions for mothers of young children reported to date (Amorim et al., 2007, Hartman et al., 2010, National Institute for Health and Clinical Excellence, 2011, National Institute for Health and Clinical Excellence, 2010) and possibly the first RCT to also assess changes in muscle strength exercise activities. Further investigation of viable physical activity interventions with this target group is recommended.

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Author Contributions

SM coordinated the trial and drafted the manuscript. JJ, PH, AH, SD, SB and AA designed the study and the contributed to the manuscript. SD and SM performed statistical analysis and interpreted the data. All of the authors contributed to the submitted version of the paper.

The authors declare that there are no conflicts of interest.

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Table 1: Demographics of study group at baseline. Continuous variables are presented as *Mean ± Standard Deviation (Count)* and categorical variables are presented as *Count (Percentage)*.

	<u>Completed</u>		<u>Withdrew</u>	
	<u>Intervention</u>	<u>Control</u>	<u>Intervention</u>	<u>Control</u>
N	249	272	145	50
Age (years)	35.9 ± 4.3 (249)	35.6 ± 4.3 (272)	34.6 ± 5 (139)	36 ± 4.3 (49)
Pregnant, Breastfeeding or Postpartum				
No	146 (58.6%)	177 (65.1%)	97 (66.9%)	38 (76%)
Yes	103 (41.4%)	95 (34.9%)	45 (31%)	12 (24%)
Parity				
1	82 (32.9%)	94 (34.6%)	60 (42.9%)	15 (30%)
2 or more	167 (67.1%)	178 (65.4%)	80 (57.1%)	35 (70%)
Body Mass Index (kg/m²)	24.9 ± 4.6 (134)	24.2 ± 4.6 (173)	24.4 ± 6.5 (92)	23.1 ± 3.2 (37)
Waist circumference (cm)	86 ± 12 (134)	84.8 ± 10.7 (173)	82.7 ± 13.6 (87)	82 ± 10.4 (34)
Waist-hip ratio (cm)	0.9 ± 0.3 (134)	0.9 ± 0.1 (173)	0.8 ± 0.1 (87)	0.9 ± 0.1 (34)
Strength Exercises Major Muscle Group				
No	197 (83.8%)	204 (78.5%)	111 (84.1%)	37 (78.7%)
Yes	38 (16.2%)	56 (21.5%)	21 (15.9%)	10 (21.3%)

Table 2: Comparison of physical activity variables (mean minutes per week) between intervention and control groups. Pre, Post and Difference are expressed as *Mean ± Standard Error (Count)*

		Intervention	Control	P-value	Group difference Mean (95% CI)
All mothers					
Vigorous	Pre	59.5 ± 5.5 (237)	81.6 ± 7.1 (265)		
	Post	76.2 ± 6.5 (237)	74.7 ± 6.7 (265)		
	Difference (Post-Pre)	16.8 ± 6.3	-7.3 ± 6.5	.008	24.1 (6.2, 42.0)
Moderate	Pre	76.5 ± 5.1 (237)	94.7 ± 6.8 (263)		
	Post	100.8 ± 6.4 (237)	94.2 ± 7.2 (263)		
	Difference (Post-Pre)	25.2 ± 6.9	1.9 ± 7.5	0.023	23.3 (3.3 , 43.4)
Vigorous, Moderate, Walking	Pre	195.1 ± 13.5 (238)	257.5 ± 17.6 (265)		
	Post	252.8 ± 16.4 (238)	243.2 ± 17.6 (265)		
	Difference (Post-Pre)	58.5 ± 15.2	-13.7 ± 14.8	.001	72.2 (30.4 , 114)
Muscle strength exercises	Pre	22 ± 2.8 (222)	24.6 ± 2.6 (250)		
	Post	19.3 ± 2.3 (222)	20.4 ± 2.4 (250)		
	Difference (Post-Pre)	-4.0 ± 2.7	-4.7 ± 2.4	.852	0.7 (-6.3 , 7.6)
Excluding mothers who are pregnant, breastfeeding or postpartum					
Vigorous	Pre	65.9 ± 7.3 (135)	80.9 ± 7.8 (172)		
	Post	88.1 ± 8.9 (135)	75.5 ± 8.1 (172)		
	Difference (Post-Pre)	21.8 ± 7.7	-5.4 ± 7.7	.014	27.3 (5.5 , 49.0)
Moderate	Pre	82.1 ± 7.2 (134)	104 ± 8.2 (170)		
	Post	99 ± 8.3 (134)	92.5 ± 8.5 (170)		
	Difference (Post-Pre)	18.1 ± 9.3	-8.2 ± 8.3	.036	26.3 (1.7 , 50.8)
Vigorous, Moderate, Walking	Pre	213.9 ± 18.3 (135)	265.3 ± 20.1 (172)		
	Post	274.5 ± 22.6 (135)	242.9 ± 21.7 (172)		
	Difference (Post-Pre)	61.6 ± 19.4	-20.3 ± 17.7	.002	82 (30.2 , 133.8)
Muscle strength exercises	Pre	21.8 ± 3.9 (121)	26 ± 3.4 (162)		
	Post	22.5 ± 3.3 (121)	23.4 ± 3.2 (162)		
	Difference (Post-Pre)	-1.5 ± 3.9	-3.7 ± 2.9	.641	2.2 (-7.2 , 11.7)

Physical activity variables: vigorous intensity, moderate (mod) intensity, walking and muscle strength exercises were calculated in minutes per week

Figure 1 - Flow chart of intervention and control participants

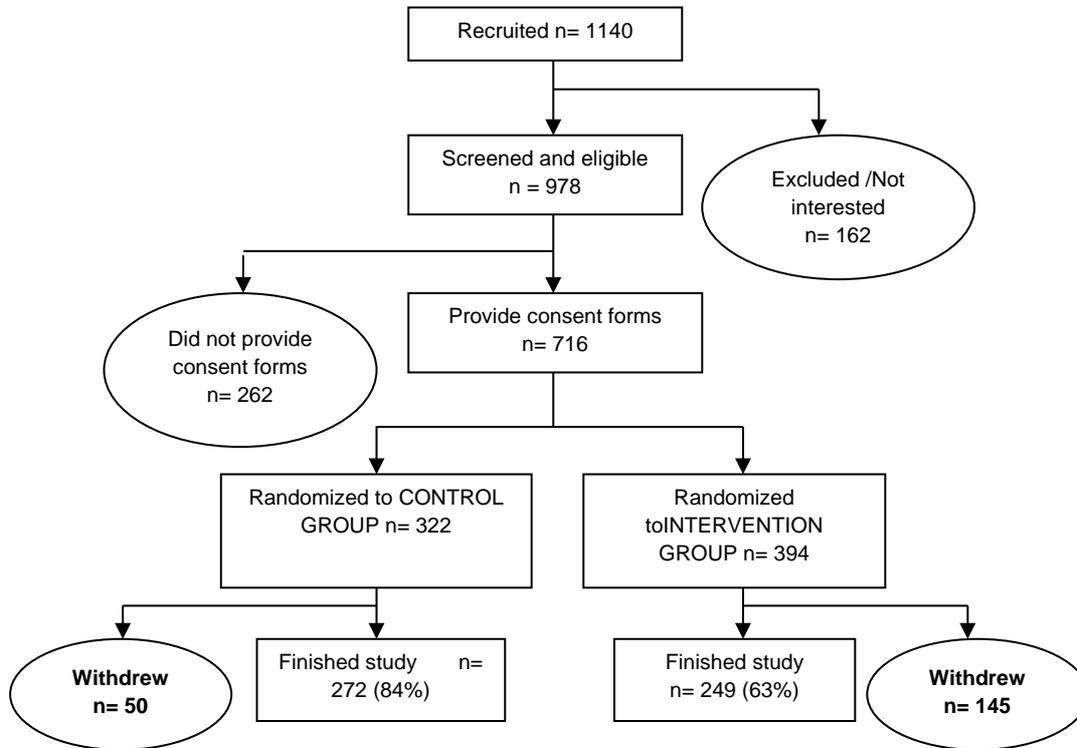


Figure 2: Net change expressed as difference between percentage of participants who improve and participants who did not improve for each type of physical activity, in both intervention (light grey colour) and control (black colour) groups.

