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LONG-TERM PHYSICAL ACTIVITY OUTCOMES OF HOME-BASED LIFESTYLE INTERVENTIONS AMONG BREAST AND PROSTATE CANCER SURVIVORS

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Abstract

Purpose—Few studies have investigated long-term effects of physical activity (PA) interventions. The goal of this study was to evaluate whether or not increased levels of moderate to vigorous physical activity (MVPA) were maintained by cancer survivors one-year after receipt of two home-based interventions.

Methods—The FRESH START trial randomized 543 breast and prostate cancer survivors to 1-of-2 mailed print diet and exercise interventions: sequentially-tailored vs. standardized (attention control). Each arm received eight mailings over a 1-year period, with follow-up at 1- and 2-years. This analysis focuses solely on the 400 participants who had suboptimal levels of MVPA at baseline (measured by the 7-Day Physical Activity Recall) and who completed the 2-year study.

Results—Median minutes of MVPA at baseline, 1-year and 2-year follow-up in the tailored intervention arm were as follows: 0, 90, and 60 mins/wk, respectively. The corresponding values in the attention-control group were 0, 30, and 30 mins/wk. Significant improvements in MVPA from baseline to 2-year follow-up were observed in both study arms ($p < 0.01$). While significant between-arm differences were observed at 1-year follow-up ($p < 0.01$), by 2-year follow-up there was only the suggestion of a trend ($p = 0.08$).

Conclusions—This study provides evidence that mailed-print exercise interventions result in significant and sustainable improvements in MVPA among newly-diagnosed cancer survivors that are observed well after the intervention is complete. While tailored interventions, as compared to

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standardized materials, appear to produce superior improvements in MVPA initially, these differences diminish over time.

Keywords

breast neoplasms; prostatic neoplasms; maintenance; physical activity; intervention; durability; exercise

Introduction

Over the past two decades, sufficient data have been collected regarding the beneficial effects of physical activity (PA) for cancer survivors both during and following treatment. Benefits include reduced symptoms and side effects, and improvements in cardiorespiratory fitness and quality of life [1]. Given the strength of evidence, the American Cancer Society has endorsed regular PA in their guidelines for cancer survivors [2, 3], and in 2010, the American College of Sports Medicine issued guidelines for PA (at least 150 minutes per week of moderate-intensity physical activity (MVPA)) in this patient population [4]. However, despite the proven benefits of PA, most cancer survivors remain sedentary [5].

In non-cancer samples, research suggests that PA intervention effects are typically short-lived, and participants return to baseline levels of PA post-intervention [6]. Several interventions that promote PA have been developed and successfully implemented among inactive cancer survivors, however the duration of these interventions have been brief and few have measured maintenance of PA levels. Of those that have evaluated maintenance, participant follow-up time has been no more than 6 months post-intervention [7–10].

The FRESH START trial compared iteratively-tailored vs. non-tailored mailed print materials in promoting PA and a healthy diet among breast and prostate cancer survivors [11, 12]. This intervention promoted 150 minutes of moderate-to-vigorous exercise/week, consumption of 5 daily servings of fruits and vegetables (F&V) and/or reduction of total and saturated fat to 30% and 10% of kcal, respectively. Intervention tailoring was based on participants' behavioral barriers, stage-of-readiness to change, progress toward goal attainment; cancer-coping style; and basic demographic characteristics. Individuals randomly assigned to the (non-tailored) attention control arm received publicly available health promotion materials. At the 1-year follow-up, when main outcomes were evaluated, both the intervention and control arms demonstrated significant increases in minutes of physical activity over baseline; however, the tailored intervention produced a significantly greater increase [12]. In the current secondary and exploratory analysis, we examine the long-term durability of increased MVPA among FRESH START participants at 2-year follow-up, 1-year after intervention completion, among those who were not sufficiently active at baseline. We hypothesized that participants in the tailored intervention would demonstrate greater sustained improvement in MVPA at 2-year follow-up compared to participants receiving non-tailored materials.

Methods

The design and main outcomes of FRESH START (conducted from July 2002 through October 2005) have been described previously [11,12]. FRESH START used an attention control design and randomized 543 breast and prostate cancer survivors to either a tailored intervention (delivery of two sequentially-tailored intervention modules focusing on either: 1) increasing F&V consumption, 2) restricting total and saturated fats, and/or 3) increasing MVPA); or to an attention control group receiving an equal number of non-tailored, publically-available brochures on diet and exercise. The FRESH START trial distributed

mailed print materials for 10 months, and conducted follow-up assessments at 1 and 2-years post baseline. There was no contact between study personnel and participants between the 1- and 2-year follow-up. This trial was approved by the Duke University Medical Center Institutional Review Board. The primary aim of the FRESH START trial was to determine if the tailored intervention resulted in significantly larger changes in lifestyle behaviors than were possible with standardized brochures in the public domain upon completion of the 1-year intervention. Indeed this was the case, and the main outcome paper that described this initial behavior change was published [12]. To date, however, the maintenance of these behavioral changes long-term has yet to be reported. This report focuses on the maintenance of MVPA, whereas a parallel manuscript evaluating the durability of dietary outcomes of FRESH START is in press [13].

Sample

Breast and prostate cancer survivors within 9-months of diagnosis were identified through self-referral, cancer registries, or oncology practices throughout North America. Patients with physician approval received a mailed invitation. Interested patients provided written informed consent, were screened, and if eligible, were enrolled into the study. Individuals were excluded from the study if they had certain conditions preventing exercise or diet modifications including; uncontrolled congestive heart failure or angina, recent myocardial infarction, breathing difficulties, walker or wheelchair use, kidney failure, progressive cancer, or non-English speaker or writer. Participants who regularly exercised and reported healthy eating habits at baseline were also excluded from the study. This analysis only includes participants who were not meeting PA recommendations at baseline, received one form of the exercise intervention (either the tailored module or the standardized materials which included exercise content), and had complete data at 1 and 2-year follow-up (N = 400). See flow diagram Fig. 1. We chose to include sedentary individuals (<150 minutes MVPA/week) because this represents the majority of cancer survivors. Baseline assessments and subsequent randomization was performed after all primary treatment was complete.

Physical activity measures

Minutes of physical activity at baseline, 1- and 2-year follow-up were measured by the *7-Day PA Recall* (PAR) via a computer-assisted telephone interview. Participants were asked to recall exercise sessions of moderate, hard, or very hard exercise that were practiced consecutively for at least 10 minutes in duration during each of the previous seven days (MVPA). When participants named various activities, the interviewer accessed the appropriate code from the Compendium of Physical Activities and determined if it met the criteria of at least five metabolic equivalent [$\text{kcal}\cdot\text{kg}^{-1}\cdot\text{h}^{-1}$] levels [14]. For all activities of at least 5 METs, participants were queried not only with regard to duration and frequency, but also intensity. In addition, they were asked to recall how much they slept each night. The remaining time for the week was presumed to have been spent in light activities [15]. Self-reported MVPA was corroborated by accelerometry on a 21% subset at all three time points: baseline, 1-year, and 2-year follow-up [16].

Statistical analyses

Baseline characteristics were calculated for continuous and categorical variables. The distribution of MVPA was not normal, thus the median and interquartile range (IQR) at each study time-point was evaluated. Comparisons between median minutes over time were compared using the Wilcoxon signed-rank test. Mann-Whitney U tests were used to compare intervention arms at each time-point. The number and proportion of individuals meeting activity recommendations at all time-points was calculated. Comparisons within each study arm over time were conducted using the McNemar test. Logistic regression was used to evaluate the association between intervention arm and improvements in MVPA

(improve vs. decrease or stay the same) at 2-year follow-up, controlling for baseline minutes of activity.

Results

In the current analysis, there were 199 individuals who were assigned to the tailored intervention arm who were not meeting exercise guidelines at baseline and who received the tailored exercise module. The remaining 72 participants from the original FRESH START intervention arm either met exercise recommendations at baseline and/or received only the fruit/vegetable and fat intervention modules, and thus were excluded from analysis in the current study. Ninety-three percent of this sample completed 1-year follow-up and 86% completed 2-year follow-up (see Fig. 1). Of study participants assigned to the attention control arm, 245 individuals were not meeting exercise recommendations at baseline and since exercise content was included in the set of standardized materials sent to control arm participants, all of these individuals received the attention control intervention. Ninety-eight percent of this sample completed 1-year follow-up and 93% completed 2-year follow-up. Thus, the available sample for this analysis was 400. Although the sample for this analysis differs slightly from the original sample, there are many similarities. The majority were female (59%), white (83%), diagnosed with stage I or stage II cancers (47% and 39% respectively), and reported a fatalist cancer coping style (57%). Moreover, the mean age was 57 ± 12 years. There were no statistically significant differences between study arms in the above mentioned baseline characteristics (Table 1).

Participants assigned to the tailored intervention arm significantly increased median minutes of MVPA from baseline to 1-year follow-up, and once the intervention was halted, reported a slight, non-significant decrease from 1 to 2-year follow-up: baseline: 0 (interquartile range: 45); 1-year: 90 (180); and 2-years: 60 (180). Figure 2. In contrast, participants assigned to the attention control arm increased and maintained their MVPA over the entire 2-year study (even after the intervention was halted): baseline: 0 (12); 1-year: 30 (111); and 2-years: 30 (150). At both 1- and 2-year follow-up, significant increases were observed compared to baseline for both arms (p -values $<.01$). Table 2. At 1-year, significant differences were observed between arms, however at 2-years only a trend ($p = 0.08$) was observed.

While all participants were sedentary at baseline, the proportion meeting goal levels of at least 150 minutes of MVPA/week increased and was maintained over time in both arms. Within the tailored intervention arm there were no differences in the proportion of participants who met guidelines at 1-year [52 (30%)] vs. 2-year follow-up [53 (31%)] (Table 2). Twenty-seven participants (16%) met recommendations at both time points. In contrast, among attention control participants, 43 (19%) met activity recommendations at 1-year and at 2-year follow-up the number was 60 (26%), which was a significant increase from 1 to 2-year ($p = 0.04$). Twenty-one participants (9%) met recommendations at both time points. Between-arm differences in the proportion meeting guidelines were observed at 1-year follow-up (0.01), however not at 2-year follow-up ($p = 0.29$).

Over half of the participants reported greater minutes of weekly physical activity at 2-year follow-up compared to baseline. Among participants who increased MVPA, the median increase was 120 minutes. Intervention assignment was not associated with increased activity at 2-year follow-up (OR: 1.26, 95% CI: 0.85 – 1.89).

Discussion

Limited data exist on the durability of exercise interventions in healthy populations, and even less among cancer survivors [6,17]. Generally adherence to an exercise intervention

decays over time [6]. Measuring exercise maintenance among cancer survivors is a relatively new area of study and the few studies available have not assessed outcomes beyond 6 months of intervention completion [7–10,17]. Our study fills a research gap by providing maintenance information at 12 months post-intervention completion among initially sedentary breast and prostate cancer survivors.

We observed two main findings in this analysis: 1) both study arms (receiving tailored and non-tailored materials) increased and maintained MVPA levels from baseline to 2-year follow-up; and 2) there was a statistically significant difference in minutes of activity between study arms at the 1-year follow-up, but not at the 2-year follow-up (due to some recidivism in those who had received the tailored intervention concurrent with some gains in those who received non-tailored materials). The fact that both study arms reported maintenance of MVPA is a novel finding given that previous studies typically report a decline in PA following the intervention, or report maintenance only among intervention arm participants (not within the control group) [7,9,10]. The successful maintenance of MVPA among both FRESH START study arms is unique across PA interventions, and its durability is likely due to the fact that the interventions were home-based and delivered over a prolonged period of time (1 year), and were delivered to participants invested in improving their health behaviors [18]. Additionally, the “teachable moment” associated with a cancer diagnosis has been reported by many [19], and may have increased consistency in health behaviors, particularly as barriers associated with recovery from treatment declined over time.

The trend toward longer-term PA maintenance with the tailored intervention is consistent with a previous study among cancer survivors [10]. Kim et al. observed significant increases in voluntary activity and energy expenditure among only the intervention group participants at post-intervention follow-up [10]. However, our findings are on the borderline and lends further support to the conclusive remarks of Muller-Riemenschneider et al. who reviewed six studies and surmised that “results were conflicting and did not provide strong evidence for favorable outcomes of tailored compared to standard interventions” [20]. Indeed, our results are most similar to the outcomes of an exercise intervention among reportedly healthy sedentary adults. Bock et al. observed an increase in PA among both study arms (an individually tailored intervention and a standard control arm) at intervention completion (6 months), and 6 months post-intervention (12 months) [18]. Significant differences between study arms were observed at 6 months, but no longer at 12 months [18].

Certainly, it is impressive that at 2-year follow-up 26% of attention control and 31% of tailored intervention participants met activity recommendations of at least 150 minutes per week, particularly since all of these survivors were sedentary at baseline. However, the converse is also true, i.e., that approximately 70% did not achieve and/or maintain goal behavior long-term. Thus, there remains a substantial subgroup of survivors who need additional assistance beyond a minimal mailed print intervention to achieve levels specified by national guidelines. Woodard et al. makes the point that long-term maintenance of positive health behaviors may not be possible among individuals whose lifestyle habits are so ingrained they are not capable of change [21]. Although, if sedentary survivors are able to increase minutes of MVPA by only a small amount, research supports the premise that any activity is better than none [22], and at all costs, to “avoid inactivity” [4]. Future interventionists may develop and organize in person or online social (support) groups for study participants with the hope of continued involvement in physical activity after intervention completion.

The primary limitations of this study are reliance on self-reported measures and the reduced sample size due to exclusions on baseline physical activity and subsequent loss of

participants at 2-year follow-up. The potential bias resulting from these limitations is mitigated by the fact that no significant differences were observed between those who completed the study vs. those who did not, and self-reported MVPA data was validated against objective measures in a subset of the sample. In addition, while light physical activity was not measured by the 7-day PAR, and could be construed as a limitation, given that current exercise guidelines are based on minutes of moderate to vigorous physical activity per week (150), we believe our study measures are in sync with current recommendations. In addition, the study's limitations are overshadowed by its strengths (i.e., strong design, theory-based intervention, and large sample size), and the fact that this study offers long-term PA outcomes in a patient population where few exist.

Conclusion

Our findings show that while tailored, as compared to standardized mailed print interventions, lead to superior short-term increases in MVPA among recently-diagnosed breast and prostate cancer survivors, both interventions lead to significant longer-term improvements in MVPA. Moreover, low cost, minimal home-based PA interventions that include print materials may result in long-term measurable PA improvements among this patient population. Maintaining activity following the completion of the intervention may be a unique characteristic of cancer survivors, and possibly due to increased strength and vigor associated with recovery and time since treatment combined with increased motivation for behavior change that accompanies a life-threatening illness. Future longitudinal research among other samples of cancer survivors and other intervention delivery modalities (internet, dvd) is needed to corroborate the premise that gains in PA can be maintained long-term and possibly throughout the balance of survivorship.

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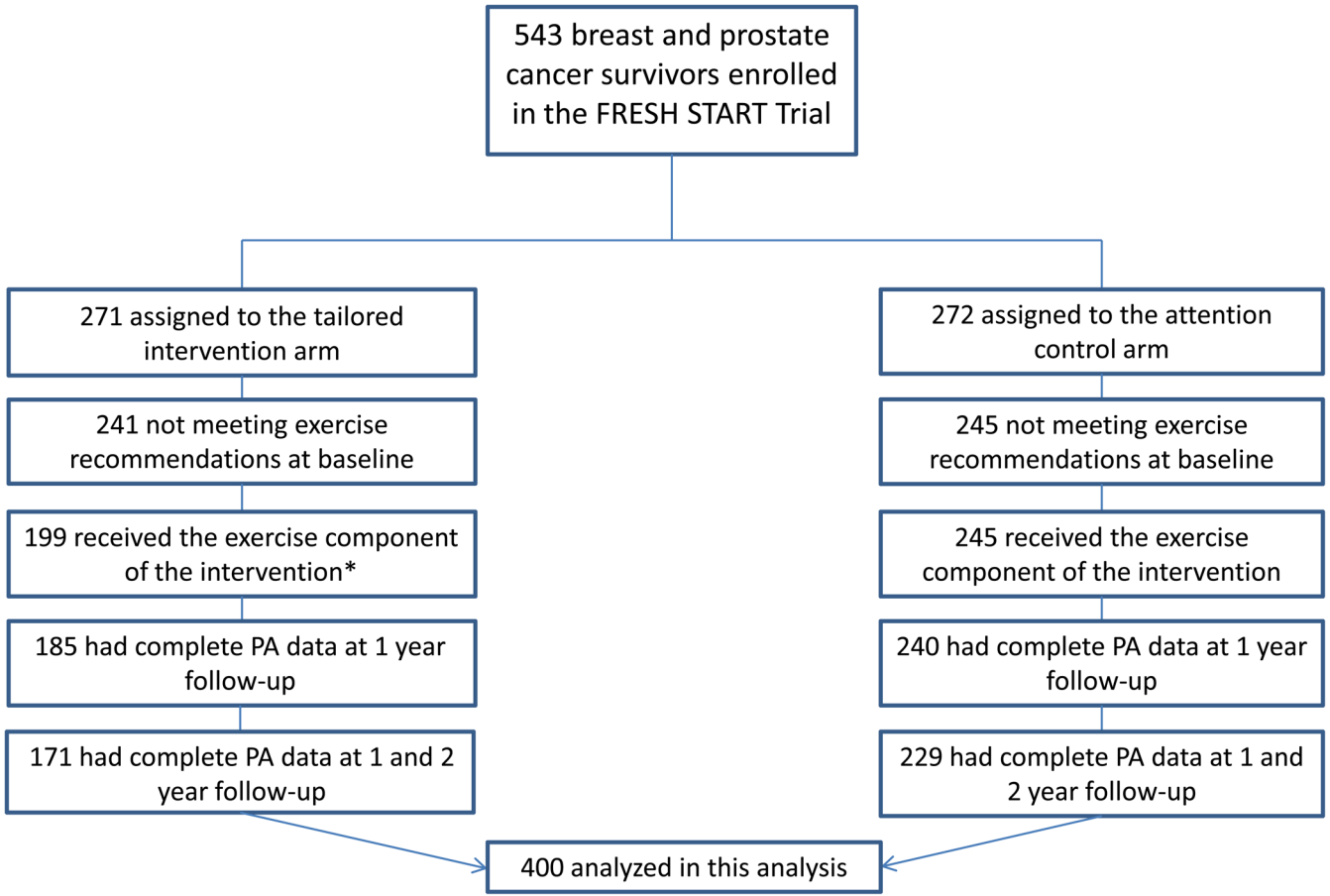


Figure 1. Flow diagram for participant inclusion in current analysis
* NOTE: Participants assigned to the tailored intervention arm received 2-out-of-3 of the following modules: Exercise, Lowfat Diet or Increased Fruit & Vegetables. Thus, some participants only received the 2 dietary modules and did not receive the exercise intervention. These participants were excluded from the analysis

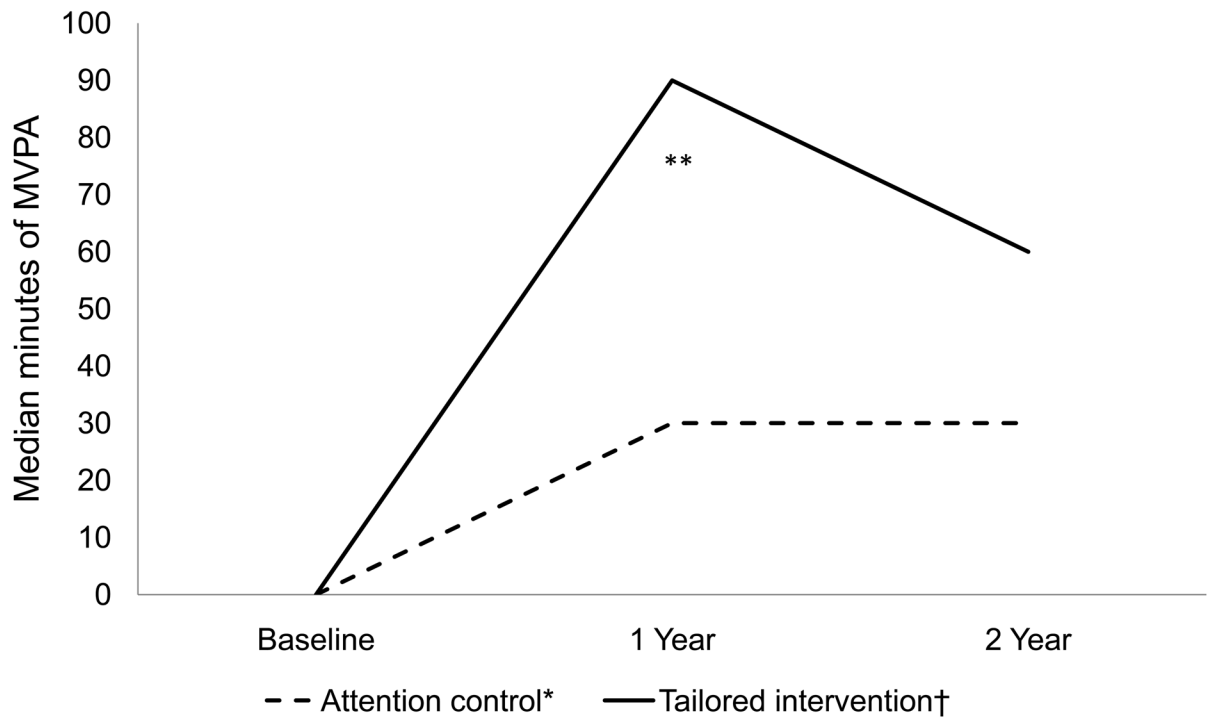


Figure 2.

Trajectory of median minutes of moderate to vigorous physical activity over time, by intervention assignment

*within this arm, significant differences were detected between baseline & 1-year follow-up ($p < 0.01$), and baseline & 2-year follow-up ($p < 0.01$)

†within this arm, significant differences were detected between baseline & 1-year follow-up ($p < 0.01$), and baseline & 2-year follow-up ($p < 0.01$)

**At 1-year, there was significant difference between attention control and tailored intervention ($p < 0.01$)

Table 1

Characteristics of the study sample (N = 400)

Characteristic	Attention Control n = 229	Tailored Intervention n = 171	P-value
	n (%)	n (%)	
Age, years			
Mean (SD)	57.1 (11.6)	58.0 (10.4)	0.43
BMI			
Mean (SD)	27.9 (5.4)	27.3 (5.3)	0.26
Comorbidities, sum			
Mean (SD)	2.2 (1.7)	2.1 (1.7)	0.44
Gender			
Male	95 (41)	69 (40)	0.82
Female	134 (59)	102 (60)	
Race			
White	191 (83)	141 (82)	0.80
Non-white	38 (17)	30 (18)	
Cancer stage			
0	20 (9)	11 (6)	0.97
1	99 (43)	87 (51)	
2	95 (41)	62 (36)	
3	5 (2)	7 (4)	
Unknown	10 (4)	4 (2)	
Treatment^a			
Radiation	94 (41)	75 (44)	0.51
Hormonal therapy	91 (40)	72 (42)	0.63
Chemotherapy ^b	62 (46)	47 (46)	0.98
Surgery	191 (83)	149 (87)	0.30
Education			
High school graduate or Less	25 (11)	19 (11)	0.82
Some college or associate	75 (33)	51 (30)	
College graduate/Postgraduate	129 (56)	101 (59)	
Cancer coping style			
Fighting spirit	79 (35)	63 (37)	0.11
Fatalist	126 (55)	100 (58)	
Other	24 (10)	8 (5)	

^aTreatment groups are not mutually exclusive^bChemotherapy was used as treatment for breast cancer only (n = 236)

Table 2

Within and between group comparisons of reported physical activity over time

	Study time point				Within group differences		
	Baseline	1-year	2-year		Baseline to 1-year	1-year to 2-year	Baseline to 2-year
					P-value	P-value	P-value
<u>PA Levels</u>							
Median (IQR) ^a							
Attention control	0 (12)	30 (111)	30 (150)		< 0.01	0.07	< 0.01
Tailored intervention	0 (45)	90 (180)	60 (180)		< 0.01	0.29	< 0.01
Between group differences							
P-value	0.24	< 0.01	0.08		-	-	-
<u>Met PA recommendations</u>							
n (%)							
Attention control	0 (0)	43 (19)	60 (26)		-	0.04	-
Tailored intervention	0 (0)	52 (30)	53 (31)		-	0.99	-
Between group differences							
P-value	-	0.01	0.29		-	-	-

^aIQR = interquartile range; the distance between the 25th percentile and the 75th percentile (range of the middle 50% of the data)