Study Design

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Exploring the effect of an eHealth intervention on women's physical activity: Design and rationale for a randomized controlled trial

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Abstract

Objective: This manuscript reports on the protocol for a three-arm randomized controlled trial aiming to assess the effect a self-determination theory-based eHealth intervention on physical activity among insufficiently active women who are overweight or obese.

Methods: The intervention-of-interest provided (A) six weekly behavioural support emails, (B) a wearable activity tracker, and (C) a copy and verbal explanation of the Canadian physical activity guidelines, and was compared to an intervention that provided (B + C) and another that provided (C). Women from a local community were invited to participate in this study. Participants were recruited between September 2018 and March 2019. Data were collected using self-report and direct measures three times: at baseline (week 0), post-intervention (week 7), and at follow-up (week 21). The primary outcome was self-reported total metabolic equivalent minutes of physical activity per week (MET-m/week); exploratory outcomes included number of days of strength training per week, self-determination theory constructs (i.e. motivational regulations, basic psychological needs satisfaction and thwarting), and well-being indicators (i.e. affect, vitality, depression).

Conclusion: Findings will provide insight into which combination of intervention components may be more effective at promoting physical activity among insufficiently active women who are overweight or obese, and thus inform the design of future interventions aiming to promote physical activity.

Keywords

eHealth, intervention, obesity, physical activity, women

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Introduction

Promoting regular physical activity (PA) participation is important because it confers health benefits and aids in weight management.[1,2] PA may reduce the risk of cardiovascular disease, diabetes, certain cancers, obesity, bone/joint diseases, and depression.[3] Globally, 23% of adults are not meeting current guidelines of 150 min of moderate-to-vigorous intensity aerobic activity (MVPA; like biking or brisk walking) per week,[4] with lower rates being observed for women who are overweight or obese.[5] It is critical to develop, evaluate, and implement tailored interventions to promote PA participation in this largely inactive segment of the population because of the links between physical inactivity and health problems.[2]

Researchers have sought to understand why women who are overweight or obese are less physically active than those who are normal weight.[5] Similar to the general population, women who are overweight or obese report low enjoyment, insufficient time, and lack of interest in PA as barriers to

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PA.[6,7] However, researchers have also found that concerns about excess weight and perceptions of weight-related prejudice may be barriers to PA for women who are overweight or obese.[6,7] Such concerns seem justified as a growing body of research shows that healthcare settings are a significant source of weight stigma,[8,9] which can undermine opportunities to receive effective weight-loss support for those who are overweight or obese. Indeed, negative stereotypes and attitudes towards those with excess weight are prevalent among healthcare providers, including PA professionals.[9] Weight bias may be explicit or explicit, and is characterized by the stereotype that those who are overweight or obese are lazy, undisciplined, unintelligent, annoying, or noncompliant with treatment.[10] Consequently, women who are overweight or obese may be reluctant to seek help to increase their PA to manage their weight, pointing to the need to develop supportive interventions to increase PA, minimize weight stigma, and improve health outcomes in this population.

PA interventions

Technology-mediated interventions, including those that provide participants with a wearable activity tracker to self-monitor their PA, are a promising strategy to promote PA in women who are overweight or obese. They would allow women to enroll in and access interventions at their convenience and engage in PA in the setting of their preference, and thus allow them to select settings that do not perpetuate weight-related prejudice. Additionally, providing women with a wearable activity tracker can facilitate self-monitoring, which is the process of directing attention towards a behaviour (e.g. step count, minutes of PA) or behavioural outcome (e.g. weight, heart rate, physical fitness, health) and keeping a record of it.[11] Upon reviewing those records, women can make informed adjustments to their behaviour to achieve their goals. This is critical as self-monitoring has been identified as a highly effective behaviour change technique in multiple systematic reviews.[12–14]

Adults in general, and specifically women who are overweight or obese, who use wearable activity trackers have been shown to increase their PA levels.[15,16] Yet, several researchers have noted that many people discontinue using wearable activity trackers over time[17–19] and that providing participants with a tracker may thwart intrinsic motivation[20] and hinder perceptions of autonomy, competence, and relatedness.[21] Thus, to maintain activity tracker use and counteract potential negative effects on motivation, researchers have implemented interventions that include additional components based on known behaviour change techniques. For example, researchers have previously provided participants with PA counselling, text messages, email-based behavioural support, and/or structured exercise programs in addition to a wearable activity tracker.[15,22] A recent meta-analysis highlighted that wearable activity tracker interventions that included additional behaviour change strategies were more effective than those which only provided a device.[15]

Such additional intervention components should be evidence-based and grounded in relevant theories, to help participants adopt health-related behaviors such as physical activity. Notably, few studies to date have examined whether an intervention grounded in *self-determination theory*[23] would be an effective addition to increase and maintain PA among women using a wearable activity tracker. Self-determination theory explains that motivation lies on a continuum from *amotivation* (i.e. the absence of motivation), through controlled (non-self-determined) motivation, to autonomous (self-determined) motivation.[23] It further stipulates that individuals reporting more autonomous motivation are more likely to be effective in self-regulating their behaviour.[23] Interventions can help individuals develop more autonomous motivation by supporting the basic psychological needs of autonomy, competence, and relatedness in various contexts, including PA.[23–25] Autonomy refers to the need to feel in control (versus feeling controlled) and to be an active participant in the decision-making process. Competence refers to the need to experience success and mastery at tasks and is typically achieved by participating in activities that are challenging but achievable. Relatedness refers to the need to feel important and connected to others. Self-determination theory-based interventions wherein researchers have sought to satisfy participants' basic psychological needs have been effective at increasing PA.[24] Whist these observations are limited in samples of women who are overweight or obese, there is evidence that theory-based interventions can lead to greater increases in PA participation,[26] and that interventions based on self-determination theory specifically show promise for increasing PA participation among women who are overweight or obese.[27,28] It is possible that targeting motivation and basic psychological needs satisfaction by providing participants with autonomy support,[29] along with a wearable activity tracker, may lead to greater increases in PA participation.

Study objectives

The main objective of the three-arm randomized controlled trial described in this manuscript is to determine if an intervention providing (A) six weekly behavioural support emails developed using tenets of self-determination theory, (B) a wearable activity tracker, and (C) a paper copy nd verbal explanation of the Canadian PA guidelines can increase PA participation among women who are overweight or obese and insufficiently active. The secondary objective is to assess if this main intervention leads to greater change in PA participation than providing (B + C) or only (C). The tertiary objective of the study is to examine if there are differences in change in self-

determination theory constructs (i.e. motivational regulations, basic psychological needs satisfaction, and thwarting) between groups.

Methods

Study design

The study is a three-arm parallel randomized controlled trial aiming to test if a 6-week self-determination theory-based eHealth intervention can lead to change in PA participation among women who are overweight or obese and insufficiently active. Participants were randomized to one of three groups (i.e. A + B + C, B + C, or C; see description above) and completed measures at three time points: at baseline (week 0), post-intervention (week 7), and at follow-up (week 21). The study duration, starting from the commencement of data collection to end was 21 weeks for participants.

Participants

The target sample size for the study was 45 women. Women were eligible to participate if they: (1) identified as female, (2) were between the ages of 18 and 65 years, (3) had a body mass index (BMI) greater than 25 kg/m^2, (4) could understand, read, and speak in English, (5) reported being able to safely engage in PA, (6) were not pregnant or lactating, (7) engaged in less than 150 min of MVPA per week and less than two muscle/bone-strengthening training sessions per week, (8) had access to internet and email, (9) had not used a wearable activity tracking device within the previous 12 months, and (10) lived within 50 km of the University of Ottawa.

Protocol

Ethical compliance, trial registration, and reporting. This manuscript describing the study protocol was prepared in accordance with the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) statement, and the manuscript reporting the main results was prepared in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized trials. An overview of the flow of participants through the study is shown in Figure 1. The study is registered in the ClinicalTrials.gov database (NCT03601663) and it was approved by the University of Ottawa Research Ethics Board (H-06-18-437).

Recruitment. Participants were recruited between September 2018 and March 2019 using advertisements on social media (e.g. Facebook, Twitter) or online boards (e.g. Craigslist, Kijiji, Newspaper Classifieds), posters placed in publicly accessible areas, and by word of mouth. A rolling recruitment strategy was used whereby participants were assessed for eligibility by telephone upon contacting the first author, and those who were eligible and willing to participate were scheduled to have their first assessment completed within 14 days of initial contact.

Randomization and blinding. The randomization sequence was generated by an independent researcher using permuted blocks of three and six using a web-based randomization software program. The authors were blinded to participants' group assignments until the baseline assessment was completed, at which point the trial was open label to allow the first author to notify participants of their group assignment and deliver the intervention.

Assessments. Participants completed assessments three times: at baseline (week 0), post-intervention (week 7), and at follow-up (week 21). Data on PA participation, self-determination theory constructs, and well-being indicators were collected using an online survey administered at each time point. Sociodemographic and health data were also collected using an online survey administered at baseline. Anthropometric measures were collected in person at baseline and post-intervention. Participants receiving weekly emails and/or a wearable activity tracker completed additional questions regarding these aspects in the online survey administered post-intervention. The assessment schedule is detailed in Table 1.

Intervention groups

The main intervention (Group 1) provided participants with (A) six weekly behavioural support emails developed based on the tenets of self-determination theory, (B) a wearable activity tracker, and (C) a paper copy and verbal explanation of the Canadian PA guidelines. The first comparison arm (Group 2) provided participants with (B) and (C). The second comparison arm (Group 3) provided participants with only (C). A paper copy and verbal explanation of the Canadian PA guidelines were provided to Group 3 due to concerns about using a no-treatment control group.[30,31] In light of this decision, the guidelines were provided to all intervention groups to ensure consistency between groups and allow for comparison of (A + B) versus only (B). The emails provided to participants in the main intervention (Group 1) contained information and activities designed to promote all types of PA (including walking, MVPA, yoga, and strength training), utilizing empirically supported behaviour change techniques.[13] They were presented so as to convey choice, opportunity for striving and success, and empathy; thereby supporting the basic psychological need for autonomy.[32] As well, participants were asked to make and adjust plans describing what, when, where, and

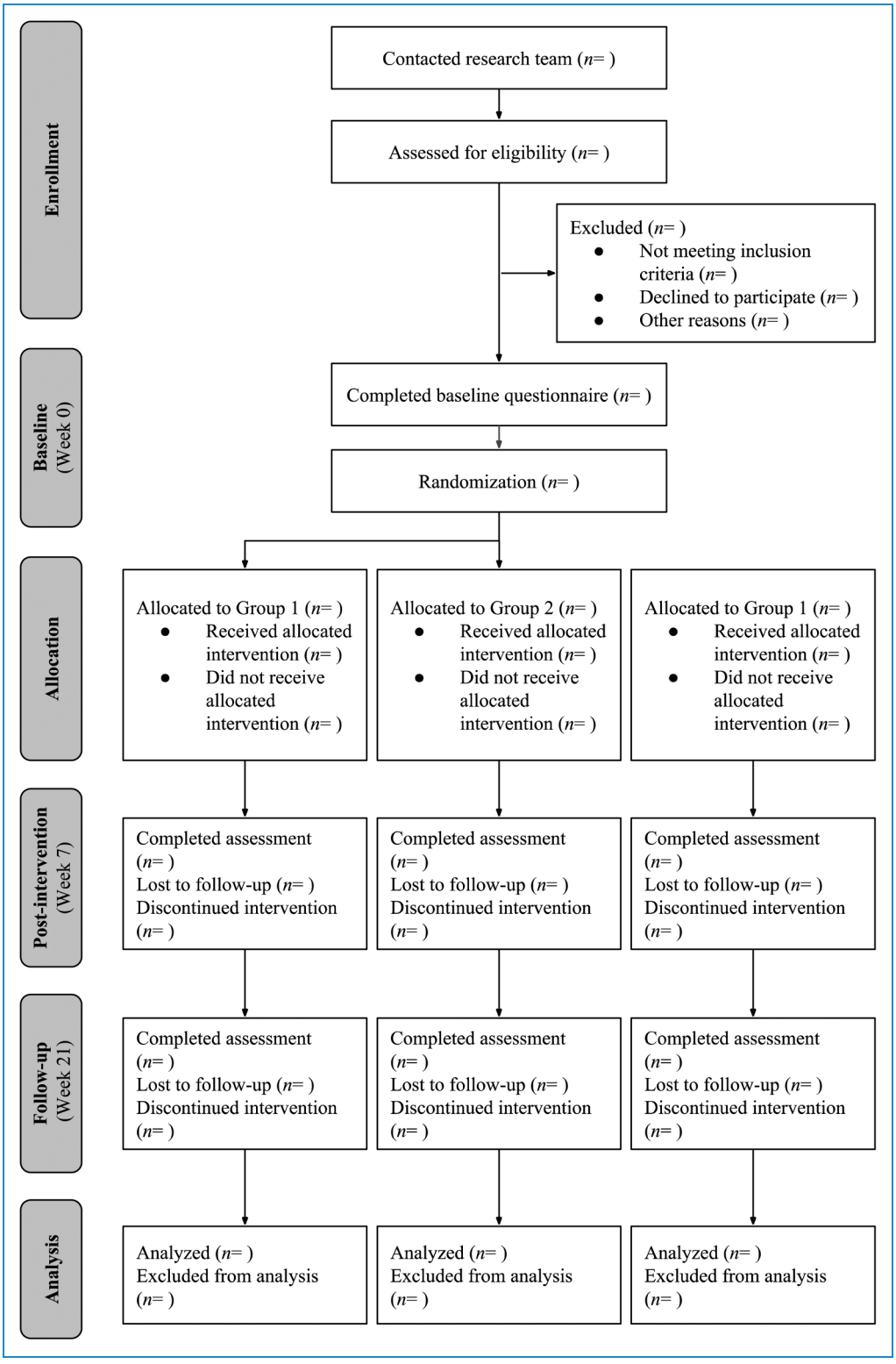

Figure 1. Template CONSORT diagram to illustrate flow of participants through the study.

with whom they planned to do their PA of choice and to make contingency plans for actual and potential barriers using if/then statements, as these may be powerful strategies for supporting competence for PA.[33] Additionally, the weekly emails encouraged participants to self-monitor their efforts towards their *behaviour* (e.g.

Table 1. Assessment schedule.

	Baseline		Post-intervention		Follow-up
Variables	Online	In-person	Online	In-person	Online
Physical activity (PA)	X		X		X
Sedentary behaviour	X		X		X
Sociodemographic information	X				
Self-reported health	X		X		X
Height		X			
Body mass	X	X	X	X	X
Body composition		X		X	
Waist circumference		X		X	
Acceptability of email intervention			X[a]		
Frequency of device use			X[b]		
Perceived autonomy support			X		
Basic psychological needs satisfaction for PA	X		X		X
Basic psychological needs frustration for PA	X		X		X
Motivational regulations for PA	X		X		X
Affect	X		X		X
Well-being	X		X		X
Depressive symptoms	X		X		X

[a]Participants in Group 1 only.
[b]Participants in Groups 1 and 2 only.

step count, frequency of activity) rather than towards *outcomes* of their behaviour (e.g. body mass, body fat percentage) because self-monitoring of *behaviour* is a robust predictor of change in PA participation based on two meta-analyses of interventions.[13,14] Content focused on obtaining social support for PA was intended to support perceptions of relatedness. A detailed overview of the weekly intervention content, as well as the behaviour change techniques used in the emails, as per the CALO-RE taxonomy11 of physical activity behaviour change techniques, are provided in Table 2. The behaviour change techniques were separately coded by the first author as well as a researcher not involved in the study. Discrepancies were resolved by discussion between both authors.

Procedures. Following the completion of the in-person baseline assessment, group allocation was revealed to participants. The first author provided participants in all groups with a paper copy of the Canadian PA guidelines along with a brief verbal explanation of the guidelines and answered any questions participants had about PA. Participants who were randomized to Group 1 or Group 2 received a Polar A300 activity monitor, a charging cable, and a username with a password to access the Polar Flow web and smartphone application. Participants were instructed to wear the device during waking hours, except when swimming or bathing, beginning the day following the in-person baseline assessment. The first author provided instructions on how to navigate the device and assisted participants in syncing the device with their smartphones. Only

Table 2. Overview of weekly emails.

Week	Purpose	Content	Behaviour change techniques included	Worksheets
1	Getting motivated for PA: To learn about the benefits and explore motives for PA	Overview of program; definitions, benefits, and recommendations for PA; self-assessment of PA behaviour; personal reasons for making a change; confidence	Provide information on consequences of behaviour in general; prompt self-monitoring of behaviour	1.1 Decisional Balance Worksheet 1.2 Importance Ruler 1.3 Confidence Ruler
2	Exploring PA: To expose the truths behind some PA myths and explore personal interests	Benefits of PA; pros and cons of making a change; personal reasons for making a change; myths about PA; choosing interesting and enjoyable types of PA	Provide information on consequences of behaviour in general; prompting focus on past success	2.1 Pros and Cons of PA Worksheet 2.2 Exploring PA Worksheet
3	Making a plan and taking action: To build an initial plan to increase PA	Personal reasons for making a change; setting SMART goals; choosing interesting and enjoyable types of PA; writing if/then statements; learning from experience	Goal setting (behaviour); action planning; agree to a behavioural contract; barrier identification/problem solving	3.1 Action Planning Worksheet
4	Adjusting your plan: To learn from previous experiences and enhance action plans	Learning from experience; barriers to PA; making small adjustments; self-monitoring; social support	Barrier identification/problem solving; prompt review of behavioural goals; prompt self-monitoring of behaviour; plan social support/social change	4.1 Week-in-review Worksheet 4.2 Barriers to PA Information Sheet 4.3 Social Support Worksheet
5	Maintaining motivation: To learn strategies to help maintain motivation in the face of challenges	Learning from experience; self-monitoring; positive and negative social support; self-talk	Prompt self-monitoring of behaviour; plan social support/social change; prompt self-talk	5.1 Self-monitoring Information Sheet 5.2 Self-talk Worksheet
6	Keep the momentum going: To review the topics covered throughout the program in preparation to continue making changes independently	Benefits and recommendations for PA; personal reasons for making a change; setting SMART goals; choosing interesting and enjoyable types of PA; writing if/then statements; learning from experience; self-monitoring; social support; long-term thinking	Provide information on consequences of behaviour in general; prompt review of behavioural goals; agree to a behavioural contract; goal setting (behaviour); action planning; barrier identification/problem solving; prompt self-monitoring of behaviour; plan social support/social change; relapse prevention/coping planning; barrier identification/problem solving;	6.1 Revised Action Planning Worksheet

PA: physical activity.

participants in Group 1 received the weekly emails throughout the study. The first email was sent the day following the in-person baseline assessment. The next email was sent one week following the previous email until all six emails were delivered. Participants in Group 2 and Group 3 received a copy of the emails subsequent to the completion of the follow-up assessment to thank them for their participation in the study.

Measures

Primary outcome

Total PA. The primary outcome of the trial is total metabolic equivalent minutes of PA per week (MET-m/week), which was assessed using the International PA Questionnaire Short Form (IPAQ-S) at baseline, post-intervention, and at follow-up. Participants were asked to report the number of days and average duration over the past week in which they engaged in sedentary behaviour, walking, and moderate and vigorous intensity PA. The number of days was multiplied by the average duration to estimate the number of minutes per week for each category. Scores for walking, moderate PA, and vigorous PA were multiplied by their energy requirements (3.3, 4.0, and 8.0 METs, respectively), and then summed to create a composite MET-m/week score. Scores on the IPAQ-S have demonstrated good reliability and validity for use in adult populations,[34] and has previously been used to assess PA in interventions with women who are overweight or obese.[35]

Secondary outcomes

To further explore and explain the results of the primary objective, with the intention of informing further intervention development and future research projects, several secondary outcomed were also assessed.

Strength training. Strength training was assessed at baseline, post-intervention, and at follow-up using a custom set of questions developed by the authors. Participants were asked to report the number of days they completed any strength or resistance activity within the previous seven days. Additionally, participants reported the average duration and the context (i.e. type of exercises, location, people) of their strength or resistance training activities using a series of open-ended and multiple-choice questions.

Affect. Affect was measured at baseline, post-intervention and at follow-up using the short form of the International Positive and Negative Affect Schedule (I-PANAS-SF).[36] Participants were asked to rate the degree to which they felt each of five positive and five negative items within the past week using a 5-point Likert scale with the following response options: (1) 'very slightly or not at all', (2) 'a little', (3) 'moderately', (4) 'quite a bit, and (5) 'extremely'. Negative items were reverse coded before averaging positive items and the reversed negative items to create a total affect score. Scores on the I-PANAS-SF have shown good psychometric properties across culturally diverse samples.[36]

Well-being. The Subjective Vitality Scale[37] was used as an indicator of well-being at baseline, post-intervention, and at follow-up. Participants were asked to rate degree to which they generally agree with seven statements using a 7-point Likert scale ranging from (1) 'not true at all' to (7) 'very true'. An average vitality score was calculated by averaging scores for all items. The Subjective Vitality Scale has shown adequate validity for use in adult populations.[38]

Depressive symptoms. The Patient Health Questionnaire (PHQ-9)[39] was used to assess the severity of depressive symptoms at baseline, post-intervention, and at follow-up. Participants were asked to indicate how often they had experienced certain symptoms of depression within the past two weeks by responding to nine items using a 4-point Likert scale with the following response options: (0) 'not at all', (1) 'several days', (2) 'more than half of the days', and (3) 'nearly every day'. A total depression score was calculated by summing the scores for each item, whereby higher scores represent a greater presence of depressive symptoms. Scores on the PHQ-9 have been shown to be valid and reliable, and this is a widely used measure of depression severity.[39]

Acceptability and device use. Post-intervention, participants allocated to Group 1 were asked what they liked, disliked, and would improve about the overall intervention through three open-ended questions. Participants allocated to Group 1 or Group 2 were asked questions regarding how often they wore the wearable activity tracker, how often they looked at their PA data on their wrist and through the web application, and how valuable they found having a wearable activity tracker.

Mechanisms of change

Perceived autonomy support for PA. Post-intervention, perceived autonomy support for PA was measured using the Perceived Autonomy Support Scale for Exercise Settings (PASSES) questionnaire[40] for participants in Group 1. For the purpose of the study, the scale was modified by replacing the words 'PE teacher' with 'facilitator', and 'active sports and/or vigorous exercise' with 'PA'. The PASSES contains 12 items assessing a broad range of autonomy-supportive behaviours, which were rated by participants on a 7-point Likert scale ranging from (1) 'strongly disagree' to (7) 'strongly agree'. A total perceived autonomy support score was calculated by averaging scores for all items. Whereas the PASSES was developed to assess

students' perceptions of their teachers' autonomy-supportive behaviours and has undergone rigorous development and validation processes,[40] it has since been used in the context of a behaviour change intervention with women and has shown good internal consistency and construct validity.[41] Of note, the protocol initially described administering the PASSES at baseline, post-intervention, and follow-up to all three groups. However, when conducting the in-person baseline assessments, the first few participants remarked that this questionnaire was difficult to complete at baseline. They found that it did not make sense answering questions about the PA facilitator before they had received any support from this study (via weekly emails). Accordingly, the authors decided to modify the protocol such that the PASSES was administered only at post-intervention (as participants were not being actively supported by the PA facilitator at baseline or post-intervention), and only to Group 1 (as participants in Group 2 and Group 3 did not receive the weekly emails). An amendment was then submitted to and accepted by the University of Ottawa Research Ethics Board.

Basic psychological needs satisfaction for PA. The extent to which participants perceived that their perceptions of autonomy, competence, and relatedness were satisfied in PA was measured using the Psychological Need Satisfaction in Exercise scale (PNSE)[42] at baseline, post-intervention, and at follow-up for participants in all three groups. The PNSE contains 18 statements divided equally into three subscales which measure perceived autonomy, competence, and relatedness for exercise. All items were rated using a 6-point Likert scale ranging from (1) 'false' to (6) 'true'. For the purpose of the study, the scale was modified by replacing the word 'exercise' with 'physical activity'. The average score was calculated for each subscale, representing individual needs satisfaction for autonomy, competence, and relatedness. A global NEES SATISFACTION score was calculated by COMPUTING the average of THE three subscale scores.[43,44] Scores on the original PNSE scale have demonstrated good structural validity and internal reliability,[42,45] which have been mirrored in a study employing a similar adaptation.[46]

Basic psychological needs thwarting for PA. The Psychological Need Thwarting Scale (PNTS)[47] was administered to participants at baseline, post-intervention and at follow-up for participants in all three groups. The scale was used to assess the extent to which participants perceived that their perceptions of autonomy, competence, and relatedness were actively inhibited by others in PA contexts, which is conceptually different than needs satisfaction.[23,47] The PNTS contains 12 items that are rated using a 7-point Likert scale ranging from (1) 'strongly disagree' to (7) 'strongly agree'. The average for all items was computed to create a global need thwarting score representing the overall extent to which basic psychological needs were inhibited. Scores on the PNTS have previously shown good reliability and validity for use in adult populations.[47]

Motivation for PA. Motivation for PA was assessed using the third version of the Behavioural Regulation in Exercise Questionnaire (BREQ-3)[48,49] at baseline, post-intervention, and at follow-up for participants in all three groups. The BREQ-3 includes twenty-four items divided into six subscales assessing all six motivational regulations. For the purpose of the study, the scale was modified replacing the word 'exercise' with 'physical activity' Participants were asked to respond to each item using a 5-point Likert scale with anchors (0) 'not true for me and (4) 'very true for me'. The average score WAS CALCULTED for each subscale, representing participants' level for each motivational regulation. Further, a relative autonomy index (RAI),50 was calculated by weighting AND COMBINING BREQ-3 subscale SCORES [i.e., amotivation (−3) + external (−2) + introjected (−1) + identified (1) + integrated (2) + intrinsic (3)] TO GIVE A DESCRIPTIVE OVERALL MEASURE OF PARTICIPANTS' MOTIVATION FOR PA, whereby higher scores represent greater autonomous motivation for PA. Scores on the BREQ-3 have been shown to have good internal consistency.[51]

Covariates and descriptive information

Sociodemographic and health information. Sociodemographic and health information were collected from participants in all three groups at baseline. Sociodemographic measures included self-reported age, sex, marital status, ethnicity, level of education, number of children (and age(s)), annual household income, and employment status. Health measures included self-reported history of chronic diseases, smoking history, menstrual status, body mass, weight-related goals, and self-rated health. Self-rated health was measured using the first question of the RAND 36-item Short Form Health Survey (SF-36),[52] which asks 'In general, how would you say your health is?' and provides five response categories: (1) 'excellent', (2) 'very good', (3), 'good', (4) 'fair', and (5) 'poor'. Self-reported body mass and health were re-assessed post-intervention and at follow-up.

Anthropometrics. Participants' height (cm), body mass (kg), body composition, and waist circumference (cm) were measured at baseline and post-intervention for participants in all three groups. Body mass and composition were measured using a hospital-grade body weight scale (TBF 300A, Tanita Corporation of America Inc., Arlington Heights, IL, USA). Participants were asked to refrain from drinking alcohol or engaging in MVPA for 12 h prior to the assessment, eating or drinking for 3 h prior to the meeting, and eating excessively or, restrictively, for

the 24 h leading up to the assessment.[53] Height was measured using a portable wall-mounted height rod (HR-200, Tanita Corporation of America Inc., Arlington Heights, IL, USA). Waist circumference was measured with a measuring tape at the visually inspected midpoint between the last rib and the iliac crest

Statistical analyses

Data analyses were performed using SPSS Statistics (IBM Corporation, Armonk, NY, USA). Initially, descriptive statistics were calculated for study variables at each time point. Continuous variables were denoted with means, standard deviations, and medians; categorical variables were denoted in numbers and percentages. For the main analyses, we used repeated measure analysis of variance (ANOVA) to examine differences within- and between-groups. Specifically, data were subjected to a 3×3 repeated measures ANOVA using one between-subject factor (intervention groups) and one within-subject factor (pre-intervention, post-intervention, and follow-up). We used simple pairwise comparisons with Bonferroni's adjustment to identify within- and between-group differences. We further analysed change in exploratory outcomes including self-determination theory constructs (i.e. motivational regulations, basic psychological needs satisfaction, and thwarting), and well-being indicators (i.e. affect, vitality, depression). Analyses were based on the intention-to-treat principle, and statistical significance levels was set to a p-value $< .05$.

Sample size

The study was to be powered based on the primary outcome of self-reported total MET-m/week. Assuming a moderate effect size (equivalent to $f = .25$) based on findings from a meta-analysis of pedometer-based PA interventions[54] and other interventions with overlapping features developed to promote PA in similar populations,[55,56] and using a design with three groups and three repeated measures, power calculations with alpha = .05, power = .80, and a correlation among repeated measures of .5 showed that this would require a total sample size of 36 (i.e. 12 per group) to analyse within-between group differences using repeated measures ANOVA. Therefore, we aimed to recruit 45 participants, which allows for 20% attrition without compromising power.

Discussion

There is overwhelming evidence to support the benefits of regular PA,[1,3] and women who are overweight or obese are one segment of the population who exhibit some of the lowest levels of PA.[5] It is therefore necessary to develop, evaluated, and implement to increase PA for this segment of the population. Given evidence that interventions that include wearable activity trackers can lead to increases in PA participation,[16] providing a wearable activity tracker to women who are overweight or obese is a promising strategy as it could enable women to engage in PA in a non-stigmatizing environment at their convenience. Using a wearable activity tracker would also support women in setting PA goals and self-monitoring their progress towards their PA goals, which has been shown to increase PA.[15,16] However, researchers have noted that PA increases may be short-lived as several studies have shown a decrease in PA following initial exposure to a wearable activity tracker.[17–19] Self-determination theory provides a critical lens to examine interventions using wearable activity trackers and develop supplemental intervention strategies to support PA maintenance. Accordingly, the three-arm randomized controlled trial described herein seeks to test if an intervention that provides women with (A) six weekly emails to enhance autonomous motivation for PA and basic psychological needs satisfaction, (B) a wearable activity tracker to support goal setting and self-monitoring, and (C) a copy and verbal explanation of the Canadian PA guidelines can increase PA participation among women who are overweight or obese and insufficiently active, and if this combined intervention is more effective than providing women with either (B) and (C) or only (C). The study also seeks to examine if there are differences in changes in self-determination theory-based constructs between groups.

The study described in this manuscript will make several noteworthy contributions to the literature. The recent popularity of commercially available wearable activity trackers has resulted in an explosion of research leveraging this technology in multicomponent interventions to increase PA in various populations,[22,57] and this study will be among the first in the field to compare the effects of providing (A) autonomy support for PA via email, (B) a wearable activity tracker, and (C) a copy and verbal explanation of the Canadian PA guidelines to providing (B + C) or only (C) by implementing a three-armed randomized controlled trial. Researchers examining the effects of eHealth interventions to promote PA have suggested that multicomponent interventions may produce stronger effects on change in PA than single-component eHealth interventions.[15] The main objective of the study will address a practical research question and provide valuable insights regarding which combination of intervention components is most effective at changing PA behaviour, which can be used to develop, modify, and enhance future interventions to promote PA participation among insufficiently active women who are overweight or obese.

Additionally, the study will contribute to a growing body of research drawing on self-determination theory to explain the success (or lack thereof) of interventions using wearable

activity trackers to increase PA participation, which is highly relevant given the strong evidence linking constructs from self-determination theory with PA.[24,58] A recent systematic review found that, on average, interventions that provide participants with wearable activity trackers can lead to increases in PA participation,[16] yet several subsequent studies have noted inconsistencies in responses to the intervention,[17,59] Drawing on research in other populations,[20,21,60] it is possible that using a wearable activity tracker without sufficient self-determined motivation for PA may lead to the device being perceived as controlling, thus leading to discontinuation of device use and inhibited change in PA. As such, the study will be among the first to examine changes in basic psychological needs satisfaction/thwarting and motivation for PA among women who are overweight or obese (and insufficiently active) and have used a wearable activity tracker to monitor their PA participation. Upon completion, the study will provide practical insight into whether a brief, email-based intervention can enhance changes in PA participation, basic psychological needs satisfaction and thwarting, motivation for PA above and beyond the provision of a wearable activity tracker.

Nevertheless, certain limitations must also be acknowledged. First, to conserve power in analyses involving self-determination theory constructs (i.e. motivational regulations, basic psychological need satisfaction, and thwarting), composite scores for these variables. Second, there may be selection bias due to the selected recruitment strategies which may have two implications for the results: the sample may not be representative of all women who are overweight or obese and women who volunteer to participate in this trial may be more motivated to increase their PA than the broader population. Third, despite the known benefits of direct measures of PA,[61] a self-report measure of PA was chosen for reasons of feasibility and to reduce the potential for contamination (as participants in Group 3 could have inadvertently made changes to their PA participation as a result of knowing they are were monitored). Finally, the assessment schedule combined with the brief duration of the intervention will only allow for exploration of short-term (i.e. less than 6 months) change in PA participation, therefore no conclusions about the long-term impact of the interventions can be made.

Despite these limitations, the study represents an important step towards the long-term need to develop interventions that have an impact on PA participation among women who are overweight or obese and insufficiently active. Using flexible delivery methods designed for participants' convenience, exploring the impact of the intervention of PA and motivation for PA simultaneously, and isolating the effect of the wearable activity tracker from other intervention components, the study will contribute important theoretical insights and allow researchers make practical recommendations for developing interventions to promote PA participation among women who are overweight or obese – an important segment of the population among whom PA participation is particularly low.

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