Investigating the Relationship between Mental Health and Goal Attainment for Individuals Participating in a Healthy Lifestyles Program: A Pragmatic Randomized Pilot Trial

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Purpose

Rates of mental illnesses are rising in Canada [1]. Lifestyle changes, including increasing physical activity, can reduce symptoms of mental illnesses [2]. Setting goals as a part of a lifestyle program is integral in changing behavior, and formulating an action plan, that outlines how the person will achieve their goals, is effective in helping individuals put their goals into action [3]. Results from a meta-analysis with 94 independent studies and more than 8000 participants indicated that an action plan had a positive effect of medium-to-large magnitude on goal achievement [4]. Specifically, an effect size of $d = 0.65$ was reported, which indicates that participants who developed both goals and an action plan had higher mean goal achievement scores, as compared to those who only set goals [4].

Past research suggests that depression results in issues initiating goal pursuit, thereby decreasing the likelihood of meeting goals [5]. This may result in frustration, hopelessness and further depression, consequently instigating a cycle of failure and depression [5]. Furthermore, another study found that depressed individuals generated less specific goals, as compared to controls [6]. The formation of less specific goals is likely to diminish the motivation associated with goal attainment and result in limited goal progress [6]. There is limited research concerning goal attainment and other mental health issues.
Access to mental health services is limited in Ontario [7], and goal setting is not common practice in primary healthcare check-ups. There is a need for a program that provides the supports for people to meet their healthcare goals while incorporating mental health considerations in lifestyle habit changes. A year-long Healthy Lifestyles Program (HLP) was developed for this purpose, and a pragmatic pilot trial was conducted. The full proposal with description of the program is published elsewhere [8]. Considering the lack of past evidence regarding the relationship between mental health and goal attainment, this current study examines how mental health issues affect the likelihood of participants meeting health goals and how participants’ meeting goals affects their mental health. Health goals relate to topics including (but not limited to): Healthy eating, physical activity, improving mood, improving sleep, managing time, socializing, and stress management. It also considers how participation in a healthy lifestyles program affects the likelihood of participants meeting health goals. This research is a part of a pilot study that is examining the feasibility and implementation of the HLP.

Research Questions

1. Is there preliminary evidence that suggests that the presence of various mental health issues, namely depression, loneliness, or insomnia affect the likelihood of participants meeting health goals over a year-long program?

2. Is there preliminary evidence that suggests a temporal relationship between goal achievement and participant scores on depression, loneliness, and insomnia scales, over a year-long program?

3. Is there preliminary evidence that suggests that the healthy lifestyles program facilitates a reduction in mental health symptomology, compared to only setting goals, over a year-long program?

4. Is there preliminary evidence that suggests that the healthy lifestyles program facilitates the achievement of health goals, compared to only setting goals, over a year-long program?

Hypotheses

We hypothesize that those with various mental health issues are less likely to meet their goals, as compared to those without various mental health issues, and that those who achieve their goals are more likely to see improvements in mental health scores over the year-long program. We also hypothesize that participants who partake in the full healthy lifestyles program are more likely to see improvements in their mental health symptoms, and are more likely to meet their health goals, as compared to those who only set health goals.

Objectives

Primary

1. To determine the association between various mental health issues (including depression, loneliness and insomnia) and the likelihood of meeting health goals.

2. To search for possible effects between meeting health goals and changes in mental health outcomes (including depression, loneliness and insomnia).

Secondary

1. To ascertain whether participation in the healthy lifestyles program affects participants’ mental health scores.

2. To investigate whether participation in the healthy lifestyles program affects the likelihood of meeting health goals.

Methods

This study was approved by the Hamilton Integrated Research Ethics Board (HiREB; #3793). This study was registered on ClinicalTrials.gov (Identifier: NCT03258138.)

Design

This study was a pilot pragmatic randomized controlled trial, with a parallel group design. The study was not blinded as it was impossible to conceal treatment group from both participants and researchers.

Sample

Fifteen participants were recruited for each arm. Inclusion criteria were English-speaking individuals over the age of 18. Exclusion criteria were unstable mental or physical health concerns. Due to the fact that this was a pragmatic trial, all other participants, including those with mental health concerns (and those taking any pharmacological treatments), were included in the analyses. No drugs were prescribed through the program, and any pharmacologic or additional psychotherapeutic prescriptions would have been by the participant’s own primary care physician. All participants provided written informed consent. Sample size was determined by accounting for the ideal number of people involved in small group sessions (8-15) and for potential attrition throughout the year. Effect size determination will be used to guide the sampling approach for a scaled-up study. Participants were assigned an ID number and randomized using the RAND function in Excel and were randomized in a 1:1 ratio. The randomization procedure was completed by a research assistant who was not involved with recruitment.

Measures

Participants filled out questionnaires that included demographic information (i.e. age) at baseline and validated health scales every three months for one year. Among other health-related quality of life and wellness scales used to evaluate the feasibility of the healthy lifestyles program, the Patient Health Questionnaire-9 (PHQ-9) was used to assess depression (with higher scores...
res indicating more severe depression) [9], the Insomnia Severity Index (ISI) was used to identify insomnia (a higher score suggests more severe insomnia) [10], and the De Jong Gierveld Loneliness Scale was used to measure loneliness (higher scores indicating increased loneliness) [11]. The loneliness score was changed so that it totalled 12 instead of 6. Insomnia and loneliness were selected as indicators because of their connection to both physical and mental health disorders. Loneliness has been related to: Depression, alcohol abuse, sleep problems, personality disorders, Alzheimer’s disease, diabetes, autoimmune disorders, and cardiovascular diseases, among others [12]. Insomnia can lead to chronic diseases, such as obesity, coronary artery disease, type 2 diabetes, hypertension, depression and anxiety [13].

In terms of goal attainment, a Likert scale of 1-7 was used for each individual goal. For instance, a participant’s goal of “increase physical activity” may have had a scale ranging from 1-exercise for 10 minutes three times per week, to 7-exercise for 20 minutes five times per week. The scale was personalized and developed based on the patient’s baseline physical activity levels, ability, motivation, and purpose for the goal, among other factors. A mean goal attainment score was calculated by totalling all goal attainment scores and dividing by the number of goals set by each participant.

**Intervention**

Participants in the intervention arm met every three months for approximately two hours in a community setting in Hamilton, Ontario, with members of the healthcare team (including a family physician trained in cognitive behavioral therapy, a dietician, and an orthopedic surgeon) in order to collaboratively develop individualized health goals, construct an action plan, and identify any facilitators and barriers to achieving their goals. Participants also met weekly for approximately one hour for group sessions with the family physician trained in cognitive behavioral therapy, where they learned a variety of health-related topics, including mindful eating, proper nutrition practices and theories of health behavior, or discussed progress on their goals and barriers to reaching their goals. If necessary, participants in the intervention arm received help in finding community programs that facilitate a healthy lifestyle. Alternatively, participants in the comparator arm met for about 30-60 minutes with a research assistant trained in theories of health behavior every three months and set health goals, formulated action plans, and identified barriers and facilitators to achieving their goals following the same format as in the intervention group. If required, the research assistant also helped participants find community programs to help support their lifestyle changes.

**Analysis**

Descriptive statistics were calculated for participants who were enrolled at baseline. In order to determine the association between mental health issues and goal attainment, separate Generalized Estimating Equation (GEE) models were run for depression, insomnia and loneliness. The difference between mean goal attainment scores at 12-months and baseline was entered as the dependent variable. The study arm and the difference between the 12-month and baseline score on the mental health scale were entered as the independent variables.

With respect to the direction of the association between mental health and goal attainment, separate simple linear regressions were conducted. Mental health predictors at an earlier time point (i.e. depression score at 3 months) were entered as the independent variable, and mean goal attainment from a later timepoint (i.e. at 6, 9, and 12 months) was entered as the dependent variable. Study arm, gender and age were entered as covariates in the regression models.

Repeated measures ANOVA were performed in order to ascertain whether there were significant changes over time in outcomes within each arm of the study.

GEE were run to determine whether participation in the intervention group affected the likelihood of participants meeting health goals. Mean goal attainment was entered as the dependent variable, while the study arm was entered as the independent variable.

A probability value of $p < 0.05$ was used to determine statistical significance. The model with the smallest QIC value was chosen as the most parsimonious model. All analyses were performed using SPSS version 25 [14]. For further information on the methods, please refer to the full study protocol [8].

**Results**

**Participants**

Fifteen participants enrolled in the comparator group and 15 participants enrolled in the intervention group. The final sample receiving treatment consisted of 9 participants in the intervention group and 7 in the comparator group. Mental health scores of participants in each arm are presented in Table 1.

**Research Question 1: The association between mental health and goal attainment**

Depression had a significant negative association with mean goal attainment ($\beta = -0.144, 95\% CI [-0.256, -0.032], p = 0.012$), after adjusting for study arm, age, and gender. The odds of participants’ attaining their goals were 0.886 times higher for every one-point decrease in participants’ PHQ-9 score. Insomnia had a significant negative association with mean goal attainment ($\beta = -0.184, 95\% CI [-0.236, -0.131], p < 0.001$), after adjusting for study arm and age. The odds of participants attaining their goals were 0.832 times higher for every
Research Question 4: The association between participation in the intervention and goal attainment

A GEE analysis indicated that compared to the comparator arm, participants in the intervention arm were more likely to meet health goals ($\beta = 1.066$, 95% CI [0.093, 2.038], $p = 0.032$), after controlling for age and gender. The odds of participants attaining their goals were 2.903 times higher for participants in the intervention group, compared to the comparator group.

Discussion

Main findings

There were significant negative associations between depression and insomnia, and goal attainment. This was in keeping with past research that found that depressive symptomatology is associated with issues...
initiating goal pursuit, which decreases the likelihood that participants meet their goals [5]. This finding was also not surprising considering the known relationship between depression and goal attainment, and the relationship that exists between depression and insomnia [15]. Both depression and goal attainment and insomnia and goal attainment change simultaneously over time, suggesting that one construct does not instigate change in the other. There was no significant association between loneliness and goal attainment.

The HLP was effective in reducing symptoms of depression, insomnia, and loneliness. While depression and loneliness scores remained relatively consistent in the comparator group, the insomnia score was significantly reduced over the 12-month period. Interventionsists in both arms completed training in CBT-insomnia and were able to address cognitive and behavioral issues related to sleep. However, most participants did not set health goals around improving sleep. Therefore, it is not known if achieving goals helps empower individuals, reducing stress, and improving sleep, or if improved sleep helps with the physical and mental functioning needed to set and achieve goals, or if this is a bi-directional effect. Those who participated in the intervention group were more likely to meet goals, compared to the comparator group. The combination of education sessions, peer support, meetings with the healthcare team, goal setting and action plan formulation aided participants in addressing their mental health concerns. As well, lifestyle programs that incorporate CBT have been shown to be effective in facilitating modification of dietary habits, weight, cardiovascular disease and diabetes risk factors [16]. For instance, the COPE (Creating Opportunities for Personal Empowerment) Healthy Lifestyles TEEN (Thinking, Emotions, Exercise, Nutrition) program incorporated educational and cognitive-behavioral skills in their 15-week program. Researchers found that teenagers who participated in the program had significantly lower BMI and depression at 12 months compared to the control group [17]. Providing participants with tools, skills and supports assisted them with improving their physical health and reducing their mental health symptoms.

Limitations

The retention rate of 53% is significant given it was a complex and intensive 12-month behavior change intervention. However, this can introduce attrition bias into the study. Also, the current study had a small sample size. Lastly, the staff and participants were not blinded to the intervention, as this was not possible due to the differences between the two arms of the study.

Future Directions

Future research could stratify individuals based on their clinical diagnosis of a mental disorder. This could help discern whether the actual presence of mental illness is associated with reduced likelihood of attaining goals, or whether the mere presence of symptomatology is sufficient to account for this association. The present study did not possess enough participants with specific clinical diagnoses to be able to explore this question. Also, it would be interesting for future research to examine other mental health issues, including anxiety, and consider their relationship with goal achievement.

Moreover, the results exhibited a significant reduction in participant-relevant outcomes, including depression, insomnia, and loneliness symptom over the course of the 12-months. Looking forward, it will be interesting to determine whether clinical outcomes (including weight, BMI, waist-hip ratio, blood pressure) also improve over longer amounts of time. It is likely that a year-long program was an insufficient amount of time to change clinical indicators, though these should be examined in the long-term.

Significance

This study highlighted the fact that mental health issues can be a barrier to individuals making health behavior changes. Participating in a lifestyle program that incorporates behavior modification and mental health strategies can help participants manage their mental health, thereby facilitating the achievement of their health goals.

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Clinical Trial Registration

ClinicalTrials.gov Identifier: NCT03258138.

Conflict of Interest Statements

The authors have no conflicts of interest to declare.

Authors’ Contribution

EA supervised this project and provided her guidance throughout the process. LM and ZS likewise contributed their insights, mainly with the analyses and with their editorial help. AS conducted the literature review, assisted with data collection and data analysis.

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