Assessment of a Chronic Disease Self-management Program to Increase Physical Activity of
Adicts with Severe Mental Illness

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INCREASING ACTIVITY IN ADULTS WITH MENTAL ILLNESS

Abstract

Compared to the general population, individuals with severe mental illness (SMI) experience excessive co-morbidities and early mortality. Sedentary lifestyle patterns and lack of integration of physical and mental health care are complicating factors. Research has demonstrated that self-management programs have the potential to increase physical activity levels of individuals with SMI and reduce the incidence of co-morbidities. The purpose of this quality improvement project was to assess a chronic disease self-management program (CDSMP) to increase physical activity of adults with SMI. A convenience sample of twelve consumers of a psychiatric rehabilitation program (PRP) in a rural area on Maryland’s Eastern Shore was utilized. Physical activity was measured by the total number of daily steps tracked with a pedometer. Results of data analysis indicated that there was no statistically significant difference in steps across the six weeks of the program, $\chi^2 (5, n = 12) = 3.685, p = .596$. However, findings confirmed that individuals with SMI are capable of using a pedometer and tracking steps on a daily basis. Of twelve participants, more than 50% tracked steps for at least three weeks of the program, four participants tracked steps for six weeks of the program, and all participants completed the program. Inspection of median values of steps of the group indicated an upward trend from week one to week four of the program, a finding that is clinically significant for individuals with SMI who are typically sedentary. An interprofessional approach supported the project and enabled linkages of key community stakeholders.

Keywords: severe mental illness; chronic disease self-management programs; physical activity
Assessment of a Chronic Disease Self-management Program to Increase Physical Activity of Adults with Severe Mental Illness

Overview

The average life span of individuals with severe mental illness (SMI) is nearly twenty-five years shorter than the general population (Knapik & Graor, 2013, p. 283). Severe mental illness (SMI) includes schizophrenia, bipolar disorder and major depression and affects an estimated 9.6 million adults, 4.1% of individuals, eighteen years or older in the United States (National Institute of Mental Health (NIMH), n.d.a.). Obesity, metabolic syndrome, and diabetes mellitus are potential complications of psychotropic medications in patients with SMI (Scott & Happell, 2011). In addition to the personal cost of co-morbidities for patients and their families with SMI, the cost to society is substantial. According to NIMH, health care costs in the United States have climbed steadily, estimated at 57.5 billion dollars in 2006 (National Institute of Mental Health, n.d.b.).

Sedentary lifestyle patterns and a lack of integration of physical and mental health care complicate the health of patients with SMI (Van Hasselt, et al., 2013). Physical inactivity is typical of patients with SMI and contributes to medical comorbidities (Kilbourne, Brar, Drayer, Xu, & Post, 2007). According to Daumit et al. (2005), patients with SMI are less active than the general population (p. 643). One strategy to reverse this trend is self-management programs that have the potential to increase physical activity levels and decrease incidence of co-morbidities. Patients who engage in self-management are self-directed and knowledgeable about their illnesses, participate in a collaborative relationship with the health care team, and are seen as the experts of their own care (Lorig & Holman, 2003).
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One example of a self-management program is the Chronic Disease Self-management Program (CDSMP). The CDSMP is an evidence-based program that enables an individual to be an active partner with a health care provider and set goals from a personal perspective (Bodenheimer, Lorig, Holman, & Grumbach, 2002). The CDSMP has been successfully implemented for patients with chronic physical and mental health conditions and consists of a series of six workshops, each lasting two and one-half hours. Topics include exercise, medications, nutrition, sleep management and communication skills (Lorig, Ritter, Pifer & Werner, 2013). Upon completion of the program, an increase in physical activity for patients with SMI is an anticipated outcome.

The purpose of this scholarly project was to evaluate the effectiveness of the CDSMP to increase physical activity among participants with SMI. Daily steps tracked with a pedometer during a six-week period measured physical activity. The pedometers were assessed for total steps during each week of the program. In addition, the project aligned with the Physical Activity Guidelines for Americans (U.S. Department of Health and Human Services, 2008).

**Theoretical Framework**

The Integrated Theory of Health Behavior Change, a mid-range theory, was selected to guide nursing practice in the context of self-management of patients with SMI (Ryan, 2009). A central proposition of the Integrated Theory of Health Behavior Change is health behavior change is enhanced by: 1) knowledge and beliefs; 2) self-regulation skills and abilities; and 3) social facilitation (Ryan, 2009, p. 164). The theory proposes that participation in self-management behaviors is critical to overall health behavior. Additionally, the importance of knowledge and beliefs is emphasized. Knowledge and beliefs refer to information related to the health condition coupled with the patient’s personal perception (Ryan, 2009) and are integral to
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self-management. Enhanced knowledge promotes self-confidence and the ability to recommend strategies as an expert member of the treatment team (Loring, Ritter, Pifer, & Werner, 2014, p. 97). These behavioral changes are prerequisites to the attainment of optimal health status. Expected outcomes include a reversal of the major health burden of severe mental illness complicated by chronic medical illness. The Theory of Integrated Behavior Change (Ryan, 2009) was a useful framework to guide the evaluation of the effectiveness of the CDSMP to improve self-management behaviors of patients with SMI. A visual depiction of the Integrated Theory of Health Behavior Change (Ryan, 2009) applied to improvement of health status of patients with SMI is attached (Figure 1).

Literature Review

The review of the literature focused on self-management programs and physical activity of individuals with SMI. Selected articles evaluated the effectiveness of the CDSMP for persons with SMI. Two studies were selected that described the success of self-management programs to enhance knowledge and improve self-regulation skills, consistent with the Integrated Theory of Health Behavior Change (Ryan, 2009). Three papers described physical activity patterns among patients with SMI, including the use of pedometers to track steps and distance.

Loring, Ritter, Pifer, and Werner (2014) reported a descriptive study of the CDSMP taught by peer leaders at ten community sites in Michigan. Participants (N = 139) were surveyed on sixteen health-related variables at the beginning of the self-management program and six months after completion. Health-related variables included somatic and mental health indicators; physician and emergency room visits; physical activity level; and participation in treatment. Forty-five percent of participants were diagnosed with bipolar disorder and frequently a secondary diagnosis of substance use disorder. Using t tests, the authors found that 62% of the
health variables related to somatic and mental health were significantly improved at six months regardless of the participant's specific psychiatric diagnosis \((p < .05)\). Although a strength of the study was a real-world setting, one weakness was the lack of a randomized control design. Results of the study demonstrated the potential of community-based, peer-led CDSMP for adults with SMI to enhance self-management behaviors.

Similarly, Druss et al. (2010) reported the results of a randomized pilot study of The Health and Recovery Peer Program (HARP), a program based on a peer-led CDSMP for adults with SMI. Several adaptations of the CDSMP were made to address special needs of persons with mental illness. For example, typical socioeconomic factors of persons with mental illness were considered in the sections on nutrition and exercise, such as healthy eating on a limited income and exercising safely at home. Druss et al. (2010) reported participants were diagnosed with “bipolar disorder (32.5%), schizophrenia (28.8%), major depression (26.3%) and PTSD (11.3%)” (p. 266). Participants \((N = 80)\) were randomized to an intervention group or a non-intervention group and interviewed at the beginning of the program and six months later. Results indicated that participants in the intervention group improved in self-management skills \((p = 0.01)\). Moreover, physical activity of the intervention group increased by forty minutes per week. Although randomization was a strength of the study, the brief follow-up period and outcome measures based on self-report were limitations (Druss et al., 2010). Results of the program underscored the potential of self-management programs for patients with SMI to improve physical activity levels in accordance with the model described by Ryan (2009).

Other selected articles described physical activity of adults with SMI. Beebe and Harris (2013) reported a nonexperimental descriptive study of physical activity among adults with schizophrenia or related disorders. Using a convenience sample of patients enrolled in a
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Community mental health clinic, baseline physical activity was measured by tracking steps with a pedometer for one week. Results of the study confirmed that adults with SMI walked approximately 50% fewer steps than the general population. Although a strength of the study was the use of pedometers to quantify physical activity of adults with SMI instead of questionnaires that rely on retrospective reports, the sample size was small and representative of only one mental health clinic, limiting generalizability.

Richardson, Aripas, Neal, and Marcus (2005) reported another descriptive study of physical activity of patients with SMI that employed a pedometer to track steps. The pretest, posttest design and a convenience sample (N=39) were used to evaluate effectiveness of an educational program delivered in community mental health settings. The nine-week program targeted lifestyle changes including exercise and diet. Each participant was given a pedometer to track steps on a daily basis. Average steps of participants were calculated at one week after the first session, and at 6 and 18-week intervals. Results indicated no significant change during the study period. However, a limitation of the study was that baseline step data was obtained by a questionnaire instead of by pedometer. Other weaknesses were the small sample size and high number of participants who did not complete the educational program. Strengths of the study were the low-cost of the intervention and the finding that patients with SMI are capable of accurately tracking steps counted by a pedometer.

Daumit et al. (2005) also reported a descriptive study of physical activity among adults with SMI compared to the general population. Data from interviews of patients with SMI (N=185) was compared to data from randomized participants of a longitudinal national health survey of the general population. During a one-month timeframe, 25% of participants with SMI reported inactivity compared to 17.5% of the general population. The authors found that walking
was the most frequent type of physical activity reported by both the participants with SMI and the general population. A strength of the study is the large size of the comparison group, however, participants with SMI were not randomized and were selected from a convenience sample. The large size of the comparison group also facilitated additional findings such as the effectiveness of a social support system to promote physical activity, a finding that is consistent with the theoretical framework of this scholarly project.

Synthesis of Evidence

A review of the literature supported the CDSMP as an example of an evidence-based practice. Outcomes of the CDSMP demonstrated improved self-management behaviors of participants with SMI in the studies by Druss et al. (2010) and Lorig et al. (2014). Both studies were implemented in community settings of established mental health programs.

In other studies, pedometers and daily step counts measured physical activity of individuals with SMI. Beebe and Harris (2013), Richardson et al. (2005), and Daumit et al. (2005) clearly described physical inactivity of individuals with SMI. Two studies, Beebe and Harris (2013) and Richardson et al. (2005), utilized a pedometer to calculate daily steps, an objective measure that is a departure from questionnaires or interviews to estimate physical activity level. Although weaknesses of the studies included convenience sampling and small sample sizes, findings support the feasibility of using a pedometer as an objective measurement of physical activity of adults with SMI. A summary of the evidence is attached (Table 1).

Methodology

The CDSMP has been evaluated in studies of individuals with chronic somatic illness such as arthritis and diabetes (Kennedy et al., 2007; Lorig and Holman, 2003), as well as chronic mental illness (Lorig et al., 2014). Interviews, surveys, and questionnaires have been used to
determine changes in self-management variables and behaviors, including physical activity
(Druss et al., 2010; Loring et al., 2014). An additional method to evaluate the effectiveness of
the CDSMP is measurement of participants' physical activity. Pedometers are a low-cost source
of objective data. They are a reliable and easy-to-use method to track an individual's total
number of daily steps (Beebe & Harris, 2012). Among patients with SMI, increased physical
activity is a low risk intervention and has the potential to improve long-term health status
through improvement of metabolic risk factors, including obesity, hyperlipidemia and
hyperglycemia (Daumit, et al., 2005).

Institutional Review Board Review

A summary of the project was submitted to the University of Maryland Baltimore's
Human Research Protections Program (HRPO) for review. The HRPO determined that the
project was not human subjects research and did not meet criteria for IRB review (IRB letter of
acknowledgment is attached, Appendix A).

Project Design

This project was a quality improvement project that utilized The Integrated Theory of
Health Behavior Change as a basis for developing an approach to determine the effectiveness of
the CDSMP for a group of individuals with SMI. The title of the CDSMP was The Living Well
Program, an evidence-based self-management program supported by the Maryland Department
of Aging (Maryland Department of Health and Mental Hygiene, 2014). The aim of the project
was to determine if the intervention increased level of physical activity as measured by the
weekly number of steps tracked by each participant's pedometer.
Sample

A convenience sample of twelve psychiatric rehabilitation program (PRP) consumers who routinely attended a rural PRP was used. According to IRB restrictions, demographic data of the population was not collected. However, in general the PRP population in this local program consists of ambulatory adults with diagnosed severe mental illness. Approximately 50% of participants are white and 50% are African American. They were between the ages of thirty and sixty years. The percentage of males and females were approximately equal (50% each).

Setting

The setting of this quality improvement project was a rural PRP located in a small town on Maryland’s Eastern Shore. The study site is a small building located within walking distance of downtown. The building allows adequate space for group meetings, office space for staff; a small kitchen and a designated area for meals. Psychiatric Rehabilitation Programs are designed to assist consumers with SMI to live independently within a community setting. Psychosocial skills and stress reduction strategies are key components of the programs (National Alliance on Mentally Ill, n.d.). Consumers at the site of this project are also enrolled in the Health Home program, a care management program designed to integrate physical and mental health care within a holistic perspective (Medicaid.gov, n.d.). A goal of the PRP as well as the Health Home Program is to build consumer self-management expertise to attain optimal health outcomes of recovery and independence. Transportation to the site is provided from surrounding areas (Crossroads Community, Inc., n.d.).

Procedures

Six months prior to the implementation of the scholarly project, the DNP student contacted a local Living Well program coordinator to discuss the feasibility of offering the program to
increasing activity in adults with mental illness

individuals with SMI at a rural PRP. After confirmation that resources were available, approval of the program by the Executive Director and Program Coordinator of the PRP program was obtained. A meeting of key stakeholders in the project was scheduled, including the PRP site coordinator, the Health Home nurse, the Living Well Program Coordinator and the DNP student. An overview of the program was presented by the Living Well Program Coordinator, including the evidence-based curriculum; the process of obtaining participant’s consent; and the training of peer facilitators. Stakeholders were informed that the Living Well program was supported by Maryland’s Department of Health and Mental Hygiene, was grant-funded and of no cost to the host (Maryland Department of Health and Mental Hygiene, 2014). Based on the alignment of The Living Well Program with PRP and Health Home objectives, the program was scheduled on Monday of the first six weeks of 2015. Logistics related to the PRP site were addressed and a meeting space was designated that allowed seating in a circular arrangement.

After approval of the CDSMP by the stakeholders, the DNP student introduced the scholarly project as a quality improvement project designed to assess effectiveness of The Living Well Program to increase physical activity level of the participants. The use of pedometers to track the steps of participants during the program was described. The DNP student clarified that she would not attend any sessions or be part of The Living Well program, in accordance with IRB restrictions. The PRP Coordinator agreed to distribute pedometers and pocket-sized calendars as well as instruct participants on pedometer use and how to record daily step totals. Flyers announcing the The Living Well Program were posted at the PRP site.

Prior to the implementation of the scholarly project, the DNP student ordered twenty Lifesource pedometers, model X1-25, at a cost of $5 each. This pedometer was selected because
of accuracy, affordability, and a seven-day memory function (Park, Lee, Ku, & Tanaka, 2014). Pocket-sized calendars were also purchased for each participant at the cost of $1 each. Specific instructions and a step log for PRP staff to record participants’ steps were placed in a binder titled “Pedometer Project”. The DNP student met with the PRP Coordinator and a staff member one week prior to the start of The Living Well Program to review the scholarly project and deliver the binder. The functions of the pedometer were also reviewed. A copy of the instructions and sample forms are included as Attachment B, C, and D.

**Intervention**

Twelve participants of the PRP program enrolled in The Living Well Program. Two trained peer leaders of The Living Well program followed the standard procedures required of the program. Weekly sessions of The Living Well Program were conducted, two and one-half hours each, for a total of six consecutive weeks, beginning January 5, 2015. Participants were taught self-management concepts that included physical activity, exercise, sleep, diet, problem-solving and communication skills (Lorig et al., 2012). Healthy snacks were provided to model healthy eating. An overview of the Living Well Program is attached as Appendix E.

PRP staff distributed the pedometers and calendars to participants following the first session of the program. The participants were instructed by PRP staff on use of the pedometer and calendar.

**Data Collection**

PRP staff recorded the total number of steps per day of each participant in the step logs. The memory function of the pedometers was utilized if the participant’s calendar was not available. Step logs were maintained on-site in a binder. At the completion of the six weeks, the
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DNP student retrieved the binder. Any identifying information was removed by the PRP staff prior to transfer of the binder to the DNP student.

Data Analysis and Results

As a short-term quality improvement project, the primary intent of data analysis was an assessment of the CDSMP to increase physical activity of adults with SMI. Data from the participants’ step logs was entered into Microsoft Excel and merged into SPSS version 22 for statistical analysis. The sample consisted of 12 participants who completed the six-week program. The mean number of steps for the group increased from week one ($M = 13,917$, $SD = 17,717$) to week four ($M = 20,113$, $SD = 26,116$). The mean number of steps of week five ($M = 13,820$, $SD = 23,411$) and week six ($M = 15,121$, $SD = 26,553$) reflected a downward dip with a slight increase in the final week. Inspection of the median values showed an upward trend from week one ($Md = 7,651$) to week four ($Md = 12,260$), and a decline in the last two weeks of the program. Appendix F illustrates steps per participant across the six-week program, and Appendix G illustrates total steps of the group across the six-week program.

A Friedman test was used to determine if there was a difference in the number of steps across the six weeks of the program (Pallant, 2010). There was no statistically significant difference in steps across the six weeks of the CDSMP, $\chi^2 (5, n = 12) = 3.685, p > 0.05)$. Upon further inspection of the data, it was noted that many of the participants had significant missing data. Thus, those participants with 50% or more missing data were excluded from the analysis. The Friedman Test was repeated to determine if there was a difference in number of steps across the six weeks of the program for this subset of participants. There was no statistically significant difference in steps, $\chi^2 (5, n = 4) = 10.571, p > 0.05$ among this group.
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From inspection of the median values, there was an increase from Monday until Thursday, and a decline the remainder of the week. Median values of Thursday ($Md = 13,638$) were numerically higher than all other days, and median values of Saturday ($Md = 4086$) were numerically lower than all other days. Number of steps across the days of the week during the program was also analyzed. Using the Friedman test, the result indicated that there was no statistically significant difference in steps across the days of the week, $\chi^2 (6, n = 12) = 10.622$, $p > 0.05$). See Appendix H for a graph of percentage of total steps per day.

Discussion

This scholarly project confirmed previous findings that individuals with SMI are capable of using a pedometer and tracking steps on a daily basis (Richardson et al., 2005). Of twelve participants, more than 50% tracked steps for at least three weeks of the program. Four participants (33%) tracked steps for all six weeks of the program. Step logs were maintained for all participants during the total six-week period. The twelve participants attended every session of the six-week program.

While there was no statistical significance, findings from this project suggest that the CDSMP may increase physical activity of individuals with SMI. Use of calendars and pedometers by participants demonstrated a positive increase in exercise and effective self-management skills for some participants. As supported by the evidence, increased physical activity has mental and physical health benefits that may provide an impetus to continue (Beebe & Harris, 2012; Bravata et al., 2007). The trend of increased steps during the first four weeks of the program implied that participants were motivated to make changes in daily patterns. For a population that is typically inactive and overweight, even a slight increase of daily activity is evidence of clinical significance (McDevitt, Snyder, Miller & Wilbur, 2006). In addition, it is
likely that participants were exposed to the added benefit of positive role modeling of the four participants who tracked steps all weeks of the program.

PRP staff supported participants in their effort to increase physical activity. For example, the PRP site coordinator integrated the CDSMP into weekly activities and recorded steps from calendars or pedometers on the step logs. Daily encounters with participants assured documentation and provided time for reminders and encouragement. As an advocate for individuals with SMI and knowledgeable of mental illness, the PRP site coordinator was in an ideal position to assume the role of change champion. According to MacIntosh-Murran and Choo (2005), a champion “extends herself to influence and sustain the changes” (p. 1336). The presence of a change champion in a PRP leadership role may promote sustainability of effects of the CDSMP.

Other champions of change were the stakeholders who collaborated to implement the CDSMP. An interprofessional approach supported the implementation of this project. This project enabled linkages of the PRP, the Health Home Program and The Living Well Program to collaboratively plan and implement a community-based program. Increased physical activity of participants was a shared goal of each program.

For this project, the Theory of Integrated Health Behavior Change (Ryan, 2009) was an ideal framework. The utilization of theory guided the implementation of this scholarly project in an area of inquiry that presented multiple challenges and sparse research. According to Lorig et al. (2014), evaluation of the CDSMP in a mental health setting was limited to one previous study. Originally designed for individuals with chronic physical illness, implementation of the CDSMP in a mental health setting was innovative. Lorig et al. (2014) reported that the CDSMP had “not been evaluated specifically with SMI populations” in the United States (p. 97). Through
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collaboration with key stakeholders, this project was tailored to the individual who faces both mental and physical health disparities. Participants were encouraged to apply self-management skills and knowledge in three settings: during the CDSMP program; during daily activities of the PRP program; and during encounters with Health Home staff. The benefits of a three-pronged approach, as well as the constant reminder of a pedometer, may have positively influenced participation as well as the level of physical activity of participants.

Limitations

This scholarly project used a convenience sample of twelve participants at one PRP site in a single rural geographic area. Limitations were a small sample size and data analysis based on one six-week period. To assure adherence to IRB restrictions, it was necessary to rely on PRP staff to distribute pedometers, provide instruction and record data. Although cost-effective, pedometers offer limited information compared to newer physical activity trackers that can sync wirelessly to a password-protected website and provide real-time analysis (Noah, Spierer, Gu, & Bronner, 2013). Pedometers are small and may be easily lost or misplaced. Accuracy of the data depended upon the wearer as well as PRP staff who transcribed daily step counts to the step logs. In addition, the novelty of the device may have affected results and contributed to the decline in steps after the fourth week of the program when the novelty diminished. Winter weather conditions in January and February presented a barrier to outdoor activity and participants had no access to indoor physical activity equipment. In consideration of the vulnerability of the participants of this project, increased stress should also be considered as potentially influencing participation and results.
Plans for Translation

Guided by the essentials of DNP practice established by the American Association of Colleges of Nursing (Chism, 2013), the DNP as leader and clinical expert is well positioned to evaluate the outcomes of this project. In the clinical role of psychiatric nurse practitioner and clinical specialist, the DNP has first-hand knowledge of the burden of mental illness and the barriers that individuals with SMI encounter within the health care system. As an advocate of individuals with SMI, the DNP is aware of the need for interprofessional collaboration and has promoted partnerships with key stakeholders within the mental health community. The DNP as educator is prepared to disseminate findings of the project and discuss lessons learned, potentially impacting local policy. Utilizing evidence-based practice, the DNP leader in the community of mental health providers is competent in building a system that will promote physical activity of individuals with SMI to improve health status. This scholarly project is a first step in that direction.

Implications for Clinical Practice

This scholarly project has taught valuable lessons that will be helpful in future quality improvement projects for individuals with SMI. For example, approval of the Executive Director of the PRP to initiate planning was critical and paved the way for establishing linkages with key stakeholders. The timing of the project coincided with efforts of The Living Well Program to offer the program on the Eastern Shore of Maryland. The interprofessional collaboration of the local PRP, The Health Home and the Living Well Program established a new partnership of mental health providers. In addition, PRP staff enthusiastically embraced the opportunity to host the CDSMP as well as track step data of participants. Assuming a major role in the scholarly project promoted internal ownership of the project by PRP staff. Replication of
the project at other local PRP sites is likely since key linkages are now established and there is no cost to the organization. Although findings suggested only a slight upward trend of physical activity, any increase of physical activity is a reversal of the typical inactivity of individuals with SMI. This project had the potential to improve health and alter lifestyle patterns.

Recommendations for next steps include continued identification of barriers to physical activity of individuals with SMI who participate in the PRP program. Mentorship by the DNP will be offered to key stakeholders. Brainstorming of strategies to reduce barriers to physical activity will be recommended, including on-site exercise equipment, collaboration with the local YMCA, and scheduling a routine exercise class. Finally, a walking program that integrates pedometer use and a weekend option may be feasible.

Conclusions

This scholarly project is an example of translation of evidence into action for individuals with SMI who are at high risk of co-morbidities and early mortality. Utilizing the Theory of Integrated Health Behavior Change (Ryan, 2009), integration of mental and physical health care needs of individuals with SMI was operationalized. Through a collaborative effort of key stakeholders, the CDSMP was implemented at a rural PRP site using a convenience sample of twelve participants with SMI. The CDSMP is one example of a self-management program that has potential to increase physical activity of individuals with SMI. Participants were given a pedometer and pocket-sized calendar to track daily steps. By using a pedometer, participants demonstrated self-management skills and received daily feedback of physical activity level. Although not statistically significant, findings indicated an upward trend of weekly steps of the group for the first four weeks of the six-week program. All participants completed the program. The DNP leader and clinical expert is in a unique position to sustain linkages of key community
Dissemination of findings to key stakeholders is planned.

**Timeline**

See Appendix I for the timeline of the project.
References


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Figure 1. Operationalization of The Integrated Theory of Health Behavior Change applied to self-management and improved health status of individuals with severe mental illness (Ryan, 2009).
Table 1

*Johns Hopkins Evidence-Based Individual Evidence Summary*

<table>
<thead>
<tr>
<th>#</th>
<th>Author</th>
<th>Date</th>
<th>Evidence Type</th>
<th>Sample &amp; Sample Size</th>
<th>Results/Recommendations</th>
<th>Limitations</th>
<th>Rating</th>
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<tbody>
<tr>
<td>1</td>
<td>Beebe and Harris</td>
<td>2013</td>
<td>Descriptive</td>
<td>Convenience N = 24</td>
<td>In patients with schizophrenia-related disorders: first use of pedometers to measure physical activity in patients with schizophrenia; confirmation of low activity level of participants: less than 5000 steps per day; high rate of obesity among participants; average number of steps was highest on day 6, the final day of the study</td>
<td>-small sample size -limited generalizability; duration of study was only one week</td>
<td>III</td>
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<tr>
<td>2</td>
<td>Daumit et al.</td>
<td>2005</td>
<td>Descriptive (cross-sectional survey)</td>
<td>Randomized N = 185</td>
<td>In adults with SMI: high prevalence of obesity less physically active than general population higher incidence of inactivity over the past month than the general population 35% of women of sample reported no</td>
<td>insufficient data related to physical activity of participants; knowledge of participants related to physical activity was not included</td>
<td>III</td>
</tr>
<tr>
<td>#</td>
<td>Author</td>
<td>Date</td>
<td>Evidence Type</td>
<td>Sample &amp; Sample Size</td>
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| 3  | Druss et al.        | 2010    | Randomized Control Trial   | Eighty adults with SMI were randomized to the intervention program (n = 41) or usual care (n = 39); majority were African American and poverty level. | - Physical activity - walking was the most frequent type of activity  
- 29% reported walking was the only form of physical activity  
- Education was associated with increased physical activity  
- Minimal social contact was associated with a low level of physical activity. | - Small sample size: the study was a pilot project;  
- Outcomes were based on self-report of participants. | I      |
| 4  | Lorig, Ritter, Pifer, and Werner | 2014    | Descriptive                | Ten community mental health centers in Michigan participated in this study of the        | Data was collected at baseline and 6 months. Improvements in health-related status.                                                                                                                                       | - Non-randomized sample; convenience                                                              | III    |
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<th>#</th>
<th>Author</th>
<th>Date</th>
<th>Evidence Type</th>
<th>Sample &amp; Sample Size</th>
<th>Results/Recommendations</th>
<th>Limitations</th>
<th>Rating Strength Quality</th>
</tr>
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<tbody>
<tr>
<td>5</td>
<td>Richardson, Avripas, Neal, and Marcus</td>
<td>2005</td>
<td>Descriptive</td>
<td>39 adults with SMI</td>
<td>Following an 18 week program on physical activity and healthy diet, data was collected by questionnaire at baseline and subsequently by pedometer step counts at 6 weeks and 18 weeks. Results indicated no significant change in daily step totals. Participants were found to be capable of maintaining daily physical activity logs. Participants expressed satisfaction with the program and cost of the study was low.</td>
<td>Method of measurement of data was not consistent during the study; Sample size was small and not randomized; convenience sample with high dropout rate; results are not generalizable.</td>
<td>III B</td>
</tr>
</tbody>
</table>
To: Gail Lemaire RE: HP-00062657

This letter is to acknowledge that the UMB IRB reviewed the information provided and has determined that the submission does not require IRB review. This determination has been made with the understanding that the proposed project does not involve a systematic investigation designed to develop or contribute to generalizable knowledge OR a human participant (see definitions below).

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are human subject research in which the organization is engaged, please submit a new request to the IRB for a determination.

Definitions –

Human Research: Any activity that either:

- Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or

- Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA
(“FDA Human Research”). Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research as Defined by FDA: Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;

- Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR

- Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:

  • Intervention means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

  • Interaction means communication or interpersonal contact between investigator and subject.

  • Private Information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

  • Identifiable Information means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information). Human Subject as Defined by FDA: An
individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used. Please keep a copy of this letter for future reference. If you have any questions, please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@som.umaryland.edu.
Appendix B

Pedometer Instructions

1. Free pedometers and calendars are provided for each participant to keep track of the steps they walk each day.

2. The pedometer will count the steps each day and start over at midnight.

3. The pedometer will clip to a belt or you can put in your pocket or in a handbag.

4. At the end of each day, write the number on the pedometer in your calendar on that date.

5. Don’t worry if you forget; the pedometer has a memory and we can get the number later.

6. It is all set and ready to go; try not to get it wet.

7. If you lose it or misplace it, please let the staff know.
### INSTRUCTIONS FOR STAFF: STEP LOGS

- Calendars will be provided for participants to write in the total number of steps from their pedometer each night.
- Please record the total number of steps each day from the participant’s calendar into this form.
- During the week, please remind participants to write in their steps each night in their calendar.

<table>
<thead>
<tr>
<th>NAME/INITIAL</th>
<th>NUMBER</th>
<th>WEEK</th>
<th>MONDAY (Day 1)</th>
<th>TUESDAY (Day 2)</th>
<th>WEDNESDAY (Day 3)</th>
<th>THURSDAY (Day 4)</th>
<th>FRIDAY (Day 5)</th>
<th>SAT (Day 6)</th>
<th>SUNDAY (Day 7)</th>
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<td>Jan 12 - 18</td>
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<tr>
<td></td>
<td></td>
<td>Jan 19 - 25</td>
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<tr>
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<td></td>
<td>Feb 2 - Feb 8</td>
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</tr>
<tr>
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## Appendix D

### STEP LOG: SAMPLE

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<th>SAT (Day 6)</th>
<th>SUNDAY (Day 7)</th>
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<td></td>
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<tr>
<td>1 (any number is ok, NOT birth day or social security number)</td>
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Appendix E

Overview of Content of The Living Well Program

Week One

- Overview of self-management
- Importance of sleep
- Action planning

Week Two

- Problem-solving
- Managing emotions
- Physical activity
- Exercise

Week 3

- Pain management

Week 4

- Ways to Breathe Better
- Nutrition
- Communication skills

Week 5

- Use of medications
- Management of Depression

Week 6

- Weight management
- Future plans

(Lorig, et al., 2012)
Appendix F

Weekly Steps by Participant
Appendix G

Total Steps across 6 weeks
Percentage of Total Steps Per Day

Monday 11.47%  Tuesday 14.80%  Wednesday 15.74%  Thursday 15.77%  Friday 12.17%  Saturday 16.79%  Sunday 13.27%
Appendix I

Timeline

- Presentation of proposal to committee on 12/1/14.

- Submission of proposal to the University of Maryland Institutional Review Board on 12/11/14.


- Analysis, synthesis and evaluation of data completed February and March, 2015.

- Submission of scholarly project manuscript to committee on March 22, 2015.

- Presentation of Scholarly Project to committee on April 13, 2015.