

**ORIGINAL ARTICLE**

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Technology-enabled collaborative care for youth with early psychosis: A protocol for a feasibility study to improve physical health behaviours

Peter Selby^{1,2,3,4,5} | Lenka Vojtila⁶ | Iqra Ashfaq⁶ | Rosa Dragonetti⁶ |
Osnat C. Melamed^{3,6} | Rebecca Carriere^{4,7} | Laura LaChance^{8,9} |
Sara Ahola Kohut^{4,10,11} | Margaret Hahn^{12,13,14} | Benoit H. Mulsant^{5,15}

¹Addictions Research Program, Centre for Addiction and Mental Health, Toronto, Canada

²Dalla Lana School of Public Health, Toronto, Canada

³Department of Family and Community Medicine, Toronto, Canada

⁴Department of Psychiatry, University of Toronto, Toronto, Canada

⁵Campbell Family Mental Health Research Institute, Centre for Addiction and Mental Health, Toronto, Canada

⁶Nicotine Dependence Clinic, Centre for Addiction and Mental Health, Toronto, Canada

⁷Trillium Health Partners, Mississauga, Canada

⁸St. Mary's Hospital Centre, McGill University, Montreal, Canada

⁹Department of Psychiatry, McGill University, Montreal, Canada

¹⁰IBD Centre, Toronto, Canada

¹¹SickKids Research Institute, Hospital for Sick Children, Toronto, Canada

¹²Department of Psychiatry, Institute of Medical Science, Toronto, Canada

¹³Banting and Best Diabetes Centre, University of Toronto, Toronto, Canada

¹⁴Mental Health and Metabolism Clinic, Schizophrenia Division, Centre for Addiction and Mental Health, Toronto, Canada

¹⁵Department of Psychiatry, Geriatric Psychiatry, University of Toronto, Toronto, Canada

Correspondence

Peter Selby, Nicotine Dependence Service,
Centre for Addiction and Mental Health
(CAMH) 175 College Street, Toronto, ON,
Canada M5T1P.

Email: peter.selby@camh.ca

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Abstract

Aim: Individuals with psychotic disorders have poorer health outcomes and die earlier due to cardiovascular diseases when compared to healthy populations. Contributing factors include low levels of physical activity, poor nutrition and tobacco smoking. Currently, patients navigate a fragmented health-care system to seek physical and mental health services, often without access to evidence-based health promotion interventions, especially in non-academic settings or rural areas, increasing client barriers at the individual and provider level. To address these gaps, we wish to test the feasibility and impact of a Technology-Enabled Collaborative Care for Youth (TECC-Y) model to improve healthy behaviours among youth with early psychosis. The model addresses geographical barriers and maldistribution of physical and mental health care. **Methods:** A randomized controlled trial, including youth (ages of 16-29) with early psychosis (diagnosed in the past 5 years) residing in Ontario, Canada. Our primary outcome is client engagement. Secondary outcomes include smoking status, physical health and nutrition. Participants are randomly assigned to either a health coach supervised by a virtual care team, or a self-directed learning group (e-platform with

psychoeducational materials). Assessments are conducted at baseline, 6, 12 and 24 weeks.

Results: This paper presents the protocol of the study. Recruitment commenced in August 2018. This study was registered on 16 July 2018 on clinicaltrials.gov (Registry ID: NCT03610087).

Conclusions: TECC-Y will determine if a technology-based collaborative care model engages youth with early psychosis, and whether this will be associated with changes in smoking, physical health and nutrition.

KEYWORDS

collaborative care, health behaviour change, health coaching, psychosis, technology

1 | INTRODUCTION

Individuals diagnosed with a psychotic disorder die 15 to 20 years prematurely than the general population primarily due to cardiovascular diseases (World Health Organization, 2019). Developmental, genetic and environmental factors put patients with serious mental illness, such as psychosis/psychotic disorders, at risk of low levels of physical activity, poor nutrition and tobacco smoking (National Institute on Drug Abuse, 2019; World Health Organization, 2012). These behaviours compound an already elevated risk of cardiovascular disease due to genetic factors and antipsychotic use, and mediate other risk factors such as diabetes, hypertension, hypercholesterolemia and obesity (Barr, Procyshyn, Hui, Johnson, & Honer, 2008; Laursen, Munk-Olsen, & Vestergaard, 2012). Metabolic dysregulation and weight gain have been reported in the first year of initiation of antipsychotic medication in youth (Correll et al., 2014; Pérez-Iglesias et al., 2014; Pramyothin & Khaodhiar, 2010). Taken together, this creates the perfect confluence of factors to support the development of obesity, Type 2 Diabetes, premature cardiovascular disease, stroke, chronic obstructive lung disease (COPD) and other major non-communicable diseases, including cancer (World Health Organization, 2019).

Systematic and coordinated early interventions and speciality care programs are vital for youth with psychosis to help improve clinical and functional outcomes (Azrin, Goldstein, & Heinsen, 2016; Kane et al., 2015; Rosenheck et al., 2016). Trajectories of long-term outcomes can be established within the critical period of 2-5 years following the onset of psychosis when the greatest response to therapeutic treatment is observed (Albert et al., 2017; Marin, 2016). Therefore, the duration of untreated psychosis is now an important modifiable risk factor to help improve the course and future outcomes of psychotic disorders (Breitborde, Moe, Ered, Ellman, & Bell, 2017). In addition, it is within this period where declines in physical health and functioning unfold.

Early psychosis programs have been established to address these issues but few youth with a new diagnosis of psychosis actually receive coordinated, continuous care (Schoenbaum et al., 2017; Srihari et al., 2014). Currently, many individuals with mental and physical health concerns navigate a fragmented and complicated health-care system to obtain care. Youth with early psychosis face barriers to

treatment in several systematic levels of health care, such as micro-levels (eg, lack of the provision of care for individualized treatment), microsystems (eg, misguided support or misdiagnosis of early symptoms), organizational levels (eg, inconsistent availability of evidence-based practices) and macrosystems (eg, stigmatization, lack of funding; Moe et al., 2018). Several recommendations have been suggested to progress the treatment of early onset psychosis, such as more accessible, comprehensive and coordinated care, however many opportunities for improving access to high-quality treatment and providing integrated, preventive care remains (Fusar-Poli, McGorry, & Kane, 2017; Kurdyak et al., 2017; Kurdyak, Vigod, Calzavara, & Wodchis, 2012; McGorry, Killackey, & Yung, 2008; Moe et al., 2018).

In the past decade, system-level changes have been implemented to improve early interventions and treatment for youth with psychosis. In Canada, the *Early Psychosis Intervention Program Standards* was published in 2011 (with a 5-year update in 2016), as well as the *Canadian Treatment Guidelines on Psychosocial Treatment of Schizophrenia in Children and Youth* in 2017. Both reports suggest using evidence-based practices (eg, cognitive-behavioural therapy), providing specialized care, comprehensive assessments and engaging family members (Lecomte et al., 2017; Ministry of Health and Long-Term Care, 2011). In the United States, the NAVIGATE program has received much attention for its multicomponent treatment model, including family education programs, individual resiliency training, supported employment and education, and individualized medication treatment (Mueser et al., 2015). Outside of North America, several countries have implemented early intervention strategies, focusing on reducing the time between psychosis onset and treatment initiation, providing individualized treatment, and the restoration of normal developmental trajectories for youth (Hughes et al., 2014; Tang et al., 2010). As such, global efforts have been made to increase access to treatment for youth with early psychosis, however, integrated care remains elusive (primarily physical health and health promotion).

Face-to-face collaborative care is one way to have "one stop access" to comprehensive mental and physical care via a multidisciplinary team (Raney, Kathol, & Summergrad, 2013; Reilly et al., 2013), involving a primary care provider, care manager and a psychiatrist or other mental health specialist (Archer et al., 2012). Collaborative Care Models (CCMs) tend to be implemented in academic or well-resourced urban centres,

creating disparities in access to care for those in suburban and rural areas (Hoeft, Fortney, Patel, & Unützer, 2018). Thus, the scalability of face-to-face CCMs dedicated to individuals with psychosis is limited. An alternative to CCMs, integrative health coaching—a counselling style that helps improve the patient's health through evidence-based cognitive and behavioural coaching principles—is successful in eliciting metabolic and lifestyle changes in individuals with psychotic disorders (Fredrikson et al., 2014). However, this resource is also not readily available in all communities. Taken together, telecommunication and internet technology could be used to create CCMs with health coaches to enable individuals with psychosis to access evidence-based holistic treatment remotely (Hoeft et al., 2018).

Several studies have used technology as a means to elicit behavioural change among youth with early psychosis (Barbeito et al., 2014; Brunette et al., 2016; Gire et al., 2016; Killackey et al., 2011; Schlosser et al., 2018); however, the focus has been primarily on improving symptom and medication adherence. These studies do not include other aspects of health (eg, physical activity, addiction, nutrition) that are vital to this population's overall stability and well-being. Conversely, Brunette, Rotondi, et al. (2016) targeted smoking cessation treatment in smokers with schizophrenia, but they did not target psychosis-related factors (eg, symptoms, medication adherence; Brunette, Ferron, Gottlieb, Devitt, & Rotondi, 2016). Thus, the lack of benefits reported by these studies could be due to the absence of a coordinated approach to interventions (ie, addressing multiple and often competing priorities to provide individualized treatment). Moreover, these programs may lack the ability to scale coordinator programs across variably funded and resourced health systems due to their design (Gerick, Kurowski, Ranson, & Mills, 2005). Often, the focus remains on a closed system of care (ie, hospital or community mental health system) with variable inclusion of other facets (eg, primary or preventative care; Subramanian, Naimoli, Matsubayashi, & Peters, 2011) although the patient has to access several systems for their overall well-being.

In summary, the implementation, accessibility and coordination of mental and physical health care among youth with early psychosis still requires improvement. Innovation using technology to augment and facilitate care is being studied but often in isolation from the various components of the health-care system. Thus, these technological innovations may end up digitizing the problems that exist in current health-care delivery models. Rathbone and Prescott's (2017) reviewed the use of technology as an intervention for physical and mental health care. They identified the need for further research to improve the design to increase the effectiveness of these interventions, rather than having them resemble psychoeducation tools (Rathbone & Prescott, 2017). Other reviews have also focused on improvements in approach (vs content) by suggested implementation of more personalized and evidence-based interventions, including comprehensiveness in care and specialized treatment plans (Bakker, Kazantzis, Rickwood, & Rickard, 2016; Cornet & Holden, 2018).

In this context, we designed a study to evaluate the role of technology-enabled collaborative care models (CCM) for youth with early psychosis by addressing several common barriers to their well-being: geographical barriers to access to treatment and preventative

services; time pressure and competing demands for the attention of providers; lack of access to holistic treatment; lack of local expertise and stigmatization. This study will evaluate the feasibility of a technology-enabled CCM and compare it to lower intensity self-help modules with e-mail support for prevention, early identification and treatment of cardio-metabolic risk factors.

1.1 | Aims

The primary aim of the study is to evaluate participant engagement with the role of technology-enabled CCM for youth with early psychosis mediated via a virtual health coach. Secondary aims include conducting a feasibility study of a high-intensity technology-enabled CCM compared to lower intensity self-help modules and email support for early identification and management of physical inactivity, poor nutrition and tobacco/nicotine use in youth, ages 16 to 29 years, with early psychosis.

1.2 | Hypotheses

The overall research question is: How does a technology-enabled CCM engage participants with early psychosis to change health behaviours (ie, physical activity, nutrition, smoking) compared to a self-directed learning group addressing these behaviours?

Therefore, we posit three hypotheses: (1) the use of an asynchronous technology-enabled CCM facilitated by a virtual health coach will increase participant engagement in addressing their physical health needs; (2) as a result, this technology-enabled CCM will improve behaviours related to physical activity, nutrition and smoking; and (3) this technology-enabled CCM will explore satisfaction of health-care providers involved in treatment of the participants.

1.3 | Ethical approval

Our research is conducted in compliance with the Declaration of Helsinki (World Medical Association, 2013). This trial was approved by the Centre for Addiction and Mental Health (CAMH; February 2018, #121-2017), the Hospital for Sick Children (SickKids; June 2019, #1000061279) and Trillium Health Partners (THP; January 2019, #914). This study was registered on 16 July 2018 on clinicaltrials.gov (Registry ID: NCT03610087).

2 | METHODOLOGY

2.1 | Study design

This is a 12-week pragmatic randomized trial of participants who meet criteria to be randomized (1:1) in one of two interventions. The study workflow is outlined in Figure 1.

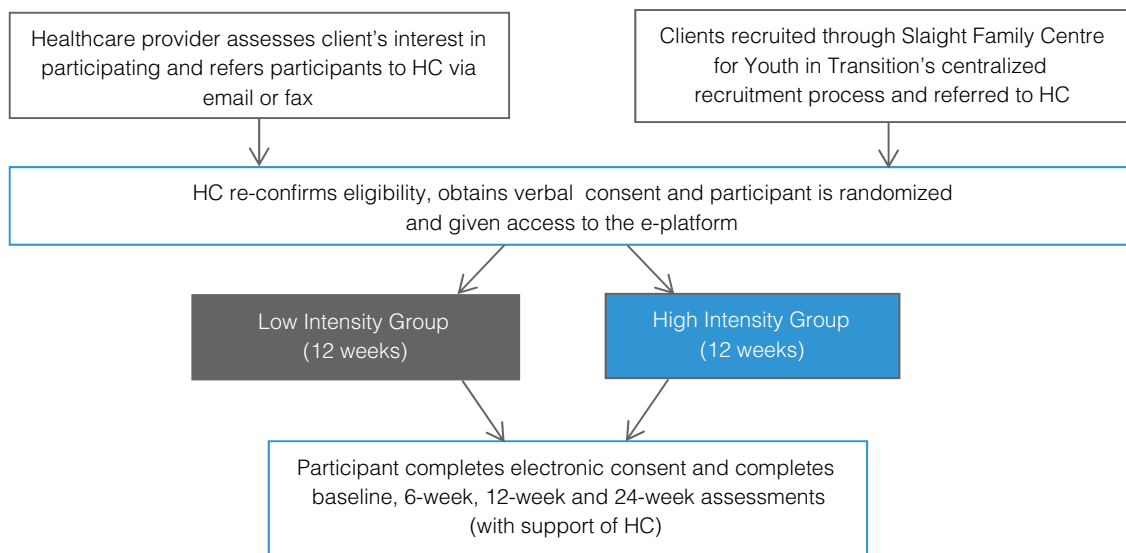


FIGURE 1 TECC-Y study workflow. HC, health coach. *Virtual Care Team: a multi-disciplinary team of health-care professionals (including a psychiatrist, addiction specialist, nutritionist, recreational therapist/personal trainer) and a peer mentor with lived experience

2.2 | Study setting

The present study is conducted online (www.mpateccy.net) or via the mobile application (available for Android users). In-person visits are not required and the participant's existing care relationships with their local providers remains uninterrupted. Participants will complete the assessments through the online platform. All study participation is conducted through the e-platform or via telephone. There is no reimbursement for participating in the study. Participants are in the study for 12 weeks and followed up at 24 weeks via the e-platform or telephone.

2.3 | Inclusion and exclusion criteria

Inclusion criteria: (a) ages of 16 to 29 years, (b) reside in Ontario (Canada), (c) clinical diagnosis of psychosis in the past 5 years, (d) currently stable on psychiatric medication (stable dose for 4 weeks), (e) have access to a telephone and/or the internet, (f) be able to provide informed consent and (g) able to understand and read English.

Participants who experience instability due to worsening psychosis are placed on hold and must be reassessed by their treating team for their capacity to rejoin the study.

2.4 | Recruitment, consent and enrollment

Informed consent is obtained from all study participants. Youth are referred from a participating hospital site (CAMH, SickKids, THP), a community agency, or via self-referral. Their treating psychiatrist, physician or health-care practitioner will provide them information about the TECC-Y study. During referral, the participant's health-care provider has the option of opting-in to receiving information about their client. After receiving the referral, the health coach screens the participant for

eligibility. After verbal consent, a capacity assessment with the participant is completed to ensure stability. A capacity assessment is completed by a health-care professional from a registered college (eg, psychotherapist). Capacity is assessed, for example, by assessing the participant's orientation (eg, date, time, year), location (eg, country, province) and comprehension of the study procedure (eg, participant rights, group randomization). Once successfully completed, participants are enrolled in the study and randomized to one of two groups. Next, participants are provided with a registration access code to register for an account on the e-platform. First, participants provide informed consent by providing their e-signature in a designated area at the end of the online consent form. Afterwards, the participants complete research assessments (up to 60 minutes to complete but may complete at their own pace) at baseline, 6, 12 and 24 weeks. Participant recruitment commenced on 1 August 2018 and will finish on 31 December 2019.

2.5 | Treatment groups and randomization

Participants are randomly assigned (1:1) into the comparison or intervention group. After participants provide verbal consent, the health coach will open the randomization envelope at the time of randomization and assign the participant to the comparison or intervention group. Please see Figure 2 for details regarding group differences, and Figure 3 for the overall technology-enabled CCM.

2.5.1 | Comparison group

The self-directed learning group (low intensity) receives access to the e-platform and is given an educational package with information about physical activity, nutrition and smoking based on the NAVI-GATE program (Mueser et al., 2015; that is, a comprehensive program

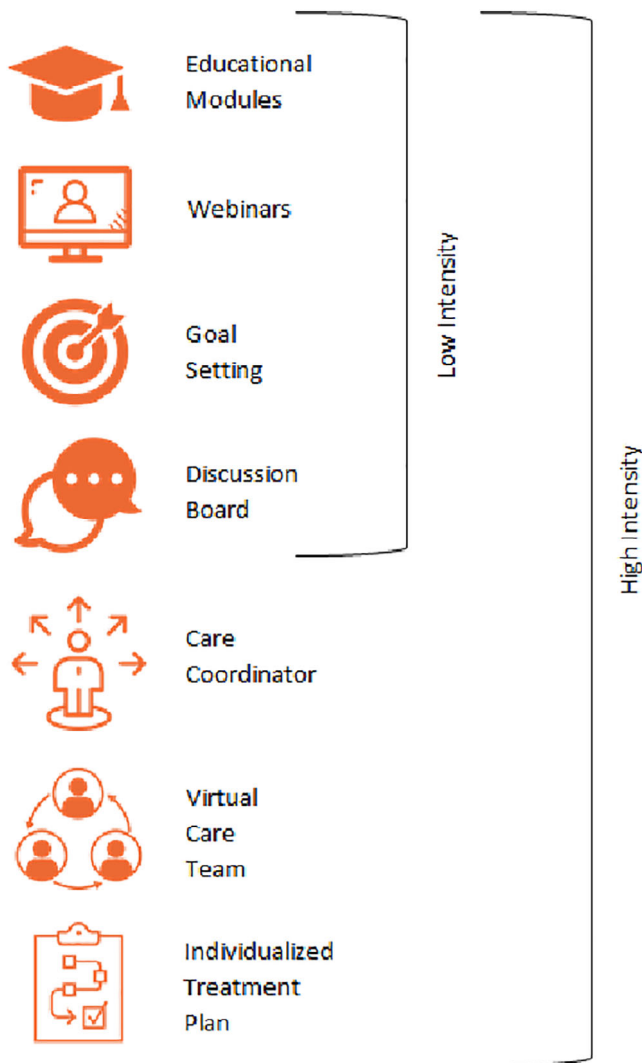


FIGURE 2 Study intervention

for implementing coordinated speciality care) with weekly automated e-mail reminders for 12 weeks. Participants receive access to online resources and free webinars about these healthy behaviours on the e-platform but no access to the health coach.

2.5.2 | Intervention group

The intervention group (high intensity) receives a technology-enabled CCM intervention. Participants receive access to an e-platform and infographic modules to learn more about physical activity, nutrition and smoking cessation. Also, they are assigned a personal health coach who collaboratively schedules weekly virtual sessions via the e-platform to discuss the educational materials, goal setting and motivation, and provides support in the 12-week program. On a weekly basis (or as needed), the health coach reviews the participant's concerns and goals with a virtual care team (VCT; including a psychiatrist, addictions specialist, nutrition specialist, peer mentor and recreational therapist). The VCT will provide individualized recommendations to

include in the participant's treatment plan. Afterwards, the health coach communicates the recommendations from the VCT to the participant for further discussion. Suggestions made by the VCT to the participant are merely recommendations. As such, participants are highly encouraged to speak with their health-care provider about these recommendations to discuss whether they should be implemented in their treatment plan. This approach helps mitigate concerns and conflicts between the VCT and the participant's providers. Please note that the participant's only source of contact in the study is with their health coach. The health coach will always speak with the participant virtually (ie, through the platform or via telephone). Lastly, participants have access to online resources and webinars about physical activity, nutrition and smoking.

A health coach's role in the participant's care includes weekly virtual call check-ins and/or ongoing communication via the e-platform, leading weekly TECC-Y Rounds with the VCT for individual case reviews, developing individual treatment plans, leading webinars and offering access to nicotine replacement therapy and/or community resources for other drug use. The health coaches strive to develop rapport with TECC-Y participants in order to facilitate engagement and enhance motivation.

3 | OUTCOME MEASURES

To measure participant engagement, we are using a visual analogue scale (available as Supporting information) to assess self-perceived benefit of changing physical activity, nutrition and smoking. This scale is included at baseline, 6-week, 12-week and 24-week assessments. Secondary measures of engagement include frequency of e-platform use through data analytics (ie, overall time participant spent on the e-platform) and engagement with the health coach (total number of calls completed among participants in the Intervention Group).

To measure baseline and outcome variables in study participants, we are using online, validated questionnaires. Measures assess domains of physical, mental and behavioural health (eg, substance use). Physical activity is determined using the Simple Physical Activity Questionnaire (SIMPAQ; Rosenbaum & Ward, 2016). The SIMPAQ estimates time spent in bed, and structured and non-structured exercise. Mood is measured using the Quick Inventory of Depressive Symptomatology (QIDS-SR; Rush et al., 2003). The Medication Adherence Rating Scale (MARS) is used to collect information on the individual's level of adherence to their psychiatric medication, a widely used measure of adherence in patients with schizophrenia (Thompson, Kulkarni, & Sergejew, 2000). Substance use data is collected using the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST). Tobacco use is measured using the Heaviness of Smoking Index (HSI), and alcohol use with the Alcohol Use Disorders Identification Test (AUDIT; Cassidy, Schmitz, & Malla, 2008). The Mediterranean Diet Adherence Screener (MEDAS) is used to measure adherence to the Mediterranean diet (Schröder et al., 2011). The Quality of Life Scale (QLS) is a semi-structured interview used to measure the participant's overall level of life purpose, motivation, and curiosity. Other data collected include demographics; list

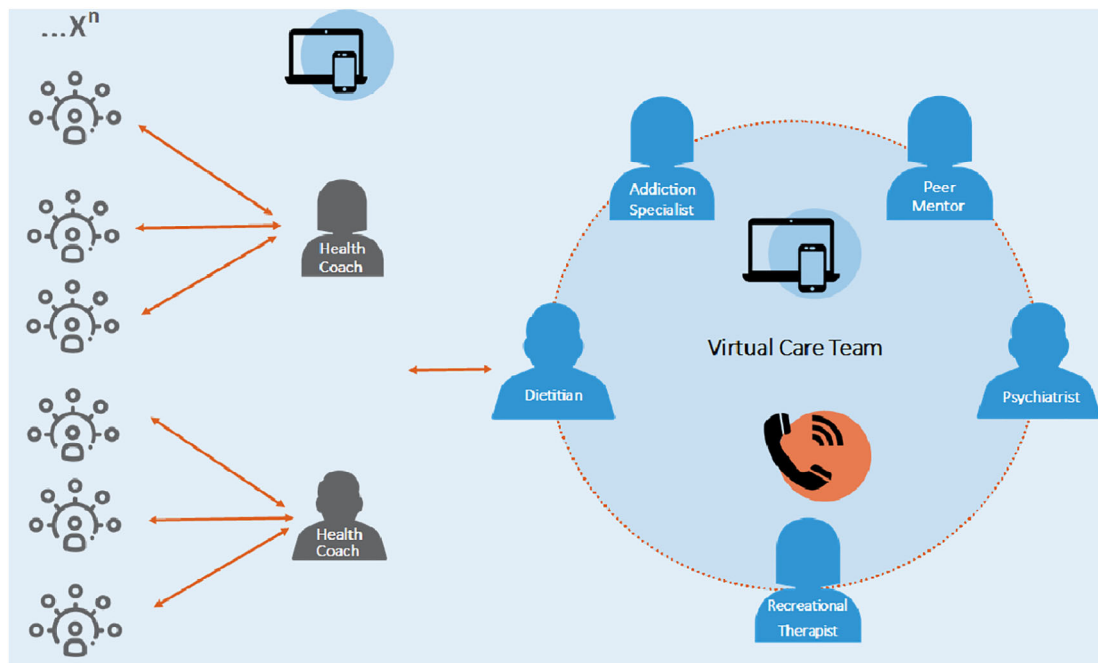


FIGURE 3 Technology-enabled CCM for high intensity (intervention group) participants

of current psychiatric medications; readiness ruler (measuring confidence, importance in making changes in physical activity, nutrition and smoking); and fitness levels based on weight, height, waist circumference and blood pressure.

Lastly, in order to measure satisfaction of health-care providers involved in the treatment of TECC-Y participants, a separate component of this study will conduct a qualitative evaluation through interviews with included and identified providers to assess overall themes, feedback and satisfaction with the process of delegating or collaborating with the VCT.

4 | SAFETY ASSESSMENT

Adverse events are recorded and reported throughout the study period. Research staff are trained in the circumstances in which a participant becomes distressed or presents with risks to self or others. Risk is mitigated through continuous clinical supervision by a registered psychotherapist and medical doctor. In addition, regular meetings with the VCT provides another layer of risk management in addition to the existing care providers of the participant. Lastly, participants will complete depression scales at each point throughout the study, which assesses low mood and suicidality. Mood is regularly assessed among participants who report lower mood and/or suicidal ideation. All concerns and updates will be provided in supervision to manage risk.

5 | RECRUITMENT STRATEGIES

Recruitment involved a series of presentations at the three hospital sites and in community agencies to inform their clinicians and staff

about the study and referral process. Posters, bookmarks and referral packages were distributed to the referral sources. A video of the TECC-Y platform was shared with referral sources and potential participants.

6 | STATISTICAL METHODS AND DETERMINATION OF SAMPLE SIZE

Data analysis will be conducted at the end of the study after intervention completion. To account for 30% attrition rate among this population (Doyle et al., 2014), the target sample size will be 120 (60 participants per group). This sample is intended to be large enough to adequately pilot the program and evaluation tools, while also constraining the likely effect sizes to inform planning of future studies.

For our primary outcome of engagement, self-perceived benefit will be analysed using linear mixed effect models with random person-level intercepts. Group differences in frequency of e-platform use will be tested using linear regression. Participant engagement with a health coach within the Intervention Group (ie, High Intensity) will be assessed using negative binomial regression, which includes total number of calls completed with the health coach in the 12-week intervention. Completion of the 12-week intervention will be analysed through retention rates. Retention in the study will be examined primarily by examining the last assessment completed by each participant. These results will be important for evaluating study validity.

For our secondary outcomes, between-group differences over time in health behaviours (physical activity, nutrition, smoking) will be examined with univariate statistics, Poisson regression and linear and ordered logistic mixed effects models, as appropriate.

For health-care provider satisfaction, conducted via qualitative interviews, the primary approach will be thematic analysis. This approach is used to identify themes within and across the interview data. Next, framework analysis will be used to compare collected documents (eg, educational and training materials) to conduct content analysis related to collaborative care intervention elements. Rigour will be used for validation once presented findings are given back to the individual teams, in order to check for the interpretation of the data. The qualitative evaluation of the study will be conducted as a separate component of the main study.

To control for potential factors that may impact the outcomes of our study, covariates for gender and referral site will be added to the analysis. Descriptive statistics will also be presented to provide demographics. The use of mixed effects models will reduce the impact of missing data, as all participants with one or more evaluations will contribute to model coefficients. Patterns of missing data will be investigated, however, and if there are grounds to suspect bias, we will use multiple imputation in our final analysis. If missingness is believed to be potentially not-at-random, we will also undertake a sensitivity analysis to explore the effects of plausible missing-data scenarios.

The study commenced on 1 August 2018. The report of the study findings are expected in 2021.

7 | DISCUSSION

This is the first study to include a technology-enabled CCM for youth with early psychosis. The primary aim of the study is to observe participant engagement, while the secondary aim is to explore whether a CCM will help facilitate healthy behavioural changes in physical activity, nutrition and smoking. Participants are all given access to the materials and tools available on the e-platform and are randomly assigned to the self-directed learning group (low intensity group) or to receive a health coach supervised by a virtual care team (high intensity group). To date, studies focusing on technology-based interventions for youth with early psychosis have primarily focused on symptom improvement and medication adherence, while failing to address other behavioural changes (ie, physical activity, nutrition and smoking). As such, our TECC-Y study proposes a new approach in order to address existing gaps in both research and in systematic levels of health care. Through the use of a technology-enabled CCM, common barriers to accessing care can be reduced and youth with psychosis can receive individualized, holistic care and psycho-education at their fingertips.

CONFLICTS OF INTEREST

The authors declare that they have no relevant competing interests. Additionally, the authors deny any interests in ForaHealthyMe Inc., which is supporting the platform and application used in this study. The authors would like to declare that the following authors on this manuscript: O. M., R. C., M. A. and B. M. are also referrers and/or treatment providers from the community sites in this study.

Unrelated to this study, Dr Selby discloses lifetime funding in receiving grants and/or salary and/or research support from the Centre for Addiction and Mental Health, Health Canada, Ontario Ministry of Health and Long-term care (MOHLTC), Canadian Institutes of Health Research (CIHR), Canadian Centre on Substance Use and Addiction, Public Health Agency of Canada (PHAC), Ontario Lung Association, Medical Psychiatry Alliance, Extensions for Community Healthcare Outcomes, Canadian Cancer Society Research Institute (CCSRI), Cancer Care Ontario, Ontario Institute for Cancer Research, Ontario Brain Institute, McLaughlin Centre, Academic Health Sciences Centre, Workplace Safety and Insurance Board, National Institutes of Health (NIH), and the Association of Faculties of Medicine of Canada. Dr Selby also reports receiving funding and/or honoraria (lifetime) from the following commercial organizations: Pfizer Inc./Canada, Shoppers Drug Mart, Bhasin Consulting Fund Inc., Patient-Centered Outcomes Research Institute, ABBVie and Bristol-Myers Squibb. Further, Dr Selby reports receiving consulting fees (lifetime) from Pfizer Inc./Canada, Evidera Inc., Johnson & Johnson Group of Companies, Medcan Clinic, Inflexion Inc., V-CC Systems Inc., MedPlan Communications, Kataka Medical Communications, Miller Medical Communications, Nvision Insight Group and Sun Life Financial. Through an open tender process Johnson & Johnson, Novartis and Pfizer Inc. are vendors of record for providing smoking cessation pharmacotherapy, free or discounted, for research studies in which Dr Selby is the principal investigator or co-investigator. Dr Mulsant currently receives research support from Brain Canada, the Canadian Institutes of Health Research, the CAMH Foundation, the Patient-Centered Outcomes Research Institute (PCORI), the US National Institute of Health (NIH), Capital Solution Design LLC (software used in a study founded by CAMH Foundation) and HAPPYneuron (software used in a study founded by Brain Canada). He directly own stocks of General Electric (less than \$5,000). Within the past 3 years, he has also received research support from Eli Lilly (medications for a NIH-funded clinical trial) and Pfizer (medications for a NIH-funded clinical trial).

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

ORCID

Peter Selby  <https://orcid.org/0000-0001-5401-2996>

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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