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A web-based mental health intervention to support recovery and prevent relapse in individuals coping with psychotic disorders: Horyzons-Canada (Phase 3)

Submission date
17/03/2021

Recruitment status
No longer recruiting

Registration date
17/03/2021

Overall study status
Completed

Last Edited
08/10/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Psychosis is a mental health condition that includes symptoms such as delusions, hallucinations, disorganized thoughts and behaviours, poverty of thought and affect, apathy, as well as deficits in verbal memory and executive functioning. The onset of psychosis typically occurs during adolescence or young adulthood (i.e., between the ages of 15-25), often leading to significant impairments in social and community functioning, and ultimately derailing transitions towards life goals. The course of the illness often involves symptom recurrence or relapse, and variable magnitudes of deterioration in social functioning. As such, psychotic disorders have been described in the literature as the most debilitating and scientifically challenging of all mental disorders.

Fortunately, we now have evidence-based psychosocial therapies as part of a comprehensive range of services and supports to optimize recovery for individuals affected by psychosis. However, psychosocial services for individuals with psychotic disorders have historically been limited to models of care that are predominantly delivered in-person. Using technologies to deliver a wide range of psychological and social interventions is needed to reduce relapses and support recovery in patients with psychosis.

The objective of this study is to assess the acceptability, safety, and potential benefits of an online psychosocial intervention (HoryzonsCa) in preventing relapses and supporting recovery in adults receiving outpatient mental health services for a psychotic disorder. We also aim to examine the experience and process of adapting and implementing (including moderator training) HoryzonsCa for two age groups (18-35, 36-50), and in a bilingual health services context.

Who can participate?
- Adults diagnosed with a psychotic disorder and who are receiving mental health services (i.e.,

under the care of a psychiatrist)
- Moderators and other members of the research team involved in adapting, implementing, or evaluating the intervention

What does the study involve?
Participants will have access to a version of the website that is adapted for use in Canada (this version of the website is referred to as HoryzonsCa). While using HoryzonsCa, participants will be able to access information and educational activities to support their recovery and reduce the risk for relapse. Participants will also be able to communicate with clinicians, peers, and a peer support worker through the website. Participants will be invited to a baseline interview to obtain sociodemographic information and baseline information about their mental health and well-being. They will also be invited to an introductory meeting to be oriented to the website before being able to use it at their convenience.

During the intervention, participants will be invited to participate in a HoryzonsCa meet-up and focus group meeting to share their experiences and perspectives of using the website (including feedback on perceived barriers and facilitators to using it).

At 3 months follow-up, participants will be invited to HoryzonsCa final interview where they will be asked the same questions about mental health and well-being asked at baseline as well as their experiences and perspectives on the website (regarding HoryzonsCa acceptability, usability, safety, and impact).

We will also collect qualitative data from the moderator and research team regarding experiences and process of adapting and implementing HoryzonsCa, through interviews and reflective narratives.

What are the possible benefits and risks of participating?
There may be a personal benefit from participating in this research project in terms of well-being and process of recovery through participation in the intervention, but this is not guaranteed. There may also be a personal benefit from participating, knowing that the results obtained will contribute to the advancement of scientific knowledge and ultimately help to improve services for others. Possible risks include the time burden of the individual interviews and group meetings, and engaging with the website. There is no risk of physical harm by participating in this study because there will be no medical procedures. However, some may experience emotional discomfort discussing topics pertaining to mental health and recovery. It is also possible that confidentiality might be broken, or sensitive information disclosed by other participants attending the focus group meeting or based on participation in the website. In order to avoid this, each participant will be asked to sign a non-disclosure agreement as part of their consent to participate, which asks him or her not to disclose information obtained from the website or the focus group discussion outside these contexts. There is also a potential risk for unlawful dissemination of participant information by unauthorized hackers, distress from inappropriate communication made by other users, increased paranoia in relation to the website (especially in the event of deterioration), and over-reliance on the website for supporting recovery. We will adapt a risk management protocol that has been shown to be highly effective with no adverse events in relation to clinical or privacy outcomes in previous studies of the intervention.

Where is the study run from?
The Psychotic Disorders Continuum Program of the Douglas Mental Health University Institute, Montreal (Canada) (thus, the main clinics would be PEPP-Montréal (First-Episode Psychosis clinic), l'Étape (outpatient clinic), four Assertive Community Treatment (ACT) teams, and the

Centre for Psychological Intervention for Psychosis (CI3P). Implementation at this site has been approved by ethics.

We also plan to add a site to our ethics protocol, which will be the Centre Hospitalier de l'Université de Montréal (CHUM), an urban super-hospital, downtown Montreal (Canada) (which includes the Clinique JAP, a well-established clinical and research program). Once we receive ethics approval to include this site in our study, we will start recruiting from this site as well.

When is the study starting and how long is it expected to run for?
May 2020 to June 2024

Who is funding the study?
Canadian Institutes of Health Research (Canada) and Hoffmann-La Roche Limited (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IUSMD-17-54

Study information

Scientific Title
Online psychosocial therapy to prevent relapses and support recovery in adults receiving mental health services for psychosis: A pragmatic feasibility study of Horyzons-Canada (Phase 3)

Acronym
HoryzonsCa Phase 3

Study objectives
Primary Objective
1. To assess the acceptability (including satisfaction, safety, and use) of HoryzonsCa.
Primary Hypothesis: HoryzonsCa will be acceptable to patients, defined as at least: 70% of participants will provide positive reports on the general experience of the platform, perceived usefulness (helpfulness), and ease of use, and at least 70% of participants will log onto the website at least 6 times over the 12 week follow-up (website usage analytics).
HoryzonsCa will be safe, defined as: 1) no adverse events, reports or incidents in relation to use of the online system from baseline assessment to 12 weeks follow-up; 2) at least 70% of participants report that they agree or strongly agree with perceived safety of the platform, and at least 70% of the participants report that they agree or strongly agree with perceived confidentiality of information shared on the platform.
We will also explore acceptability, safety, and use by qualitatively assessing experiences and perceptions of the HoryzonsCa platform from the perspectives of patients and moderators.

Secondary Objectives
2. To assess potential benefits of HoryzonsCa.
Secondary Hypothesis: Participants using the HoryzonsCa platform will show moderate to large improvements (cohen's d ≥0.5) on secondary outcome measures of: 1) positive and negative symptoms of psychosis (the 6-item Positive and Negative Syndrome Scale), 2) social functioning (interviewer-administered Personal and Social Performance Scale), 3) social support (the 12-item Multidimensional Scale of Perceived Social Support), 4) loneliness (the 20-item UCLA Loneliness Scale (Version 3), 5) depression (the 9-item Patient Health Questionnaire (PHQ-9), 6) anxiety (the 5-item Overall Anxiety Severity and Impairment Scale), 7) self-esteem (the 20-item Self-Esteem Rating Scale Short Form, the 14-item Strengths Use Scale, and the 8-item Strengths Knowledge Scale), and 8) psychological well-being (the 14-item Warwick-Edinburgh Mental Well-Being Scale) from baseline to 12 weeks follow-up. These outcomes are based on areas conceptually targeted by the platform.
3. To examine the experience and process of adapting and implementing (including moderator training) HoryzonsCa for two age groups (18-35, 36-50), and in a bilingual health services context. We will also explore the role of sex, gender, and other sociocultural and demographic factors (e.g., language) on the implementation of HoryzonsCa and related outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/12/2020, Research Ethics Board of the Douglas Mental Health University Institute (6875, boulevard LaSalle, FBC 1116, Montréal (Québec) H4H 1R3, Canada; +1 (514) 761-6131 ext. 2708; Cer.Reb@douglas.mcgill.ca) ref: IUSMD-17-54

Study design
Uncontrolled single-group pre-post mixed-methods (QUAN-QUAL convergent) design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychotic Disorders

Interventions
HoryzonsCa integrates online social networking, interactive evidence-based online interventions and expert and peer moderation in a coherent platform designed to extend the benefits of face-to-face interventions and promote long-term social functioning.

Specifically, it includes the following components:
(i) Interactive psychosocial interventions that are informed by evidence-based psychosocial interventions targeting key risk factors and salient domains in the early recovery process including: (a) psychoeducation, (b) vocational recovery, (c) early warning signs of relapse (EWS), (d) depression, (e) social anxiety, and (f) personal strengths;
(ii) Peer-to-peer online social networking including a web feed where participants and moderators can post comments and information, upload pictures and videos, and 'like' different content. Moreover, the system includes a 'wall' function displaying the activity of individual participants and a 'network' (similar to a 'friends' function on Facebook);
(iii) Moderation: HoryzonsCa incorporates two types of moderation: Clinician moderation and Super-user/peer-moderation.

HoryzonsCa adopts a strengths-based approach whereby users are guided through interactive games to identify, discuss and exercise key personal strengths within the online environment and in real-life to address both relapse risk factors and psychological well-being. Importantly, HoryzonsCa adopts an action-based approach, in which participants are prompted to practice newly acquired skills through over 350 purpose-developed behavioural activities. These are designed to bridge the gap between online therapy and real-world outcomes.

Prior to the study implementation, we will finalize our training and implementation strategy and related materials in collaboration with the moderation team.

Participants will have access to a version of the website that is adapted for use in Canada (this version of the website is referred to as HoryzonsCa). While using HoryzonsCa, participants will be able to access information and educational activities to support their recovery and reduce the risk for relapse. Participants will also be able to communicate with clinicians, peers, and a peer support worker through the website. Participants will be invited to a baseline interview to obtain sociodemographic information and baseline information about their mental health and well-being. They will also be invited to an introductory meeting to be oriented to the website before being able to use it at their convenience.

During the intervention, participants will be invited to participate in a HoryzonsCa meet-up and focus group meeting to share their experiences and perspectives of using the website (including feedback on perceived barriers and facilitators to using it).

At 3 months follow-up, participants will be invited to HoryzonsCa final interview where they will be asked the same questions about mental health and well-being asked at baseline as well as

their experiences and perspectives on the website (regarding HoryzonsCa acceptability, usability, safety, and impact).

We will also collect qualitative data from the moderator and research team regarding experiences and process of adapting and implementing HoryzonsCa, through interviews and reflective narratives.

Intervention Type
Behavioural

Primary outcome(s)
1. Acceptability (perceived ease of use, perceived usefulness, and safety), assessed by the following:
1.1. HoryzonsCa Acceptability, Usability, Safety, and Impact Questionnaire (HC-AUSI-Q), a questionnaire and semi-structured interview that includes questions on perceived ease of use, perceived usefulness, enjoyment, and safety. This will be assessed at the 12-week follow-up (HoryzonsCa Final Interview)
1.2. Website usage analytics, in terms of frequency, duration and patterns of use over the study follow-up (i.e., 3 months)

2. Safety, assessed using:
2.1. Specific questions (i.e., I felt safe using HoryzonsCa, I felt like the information shared on HoryzonsCa was confidential) in the HC-AUSI-Q. This will be assessed at the 12-week follow-up
2.2. Any incidents and adverse events in relation to the use of the online system will be carefully monitored and quantified over the study follow-up (i.e., 3 months)

Key secondary outcome(s))
1. Social functioning, measured at baseline and at 12-week follow-up using the following:
1.1. Personal and Social Performance Scale (PSP)
1.2. Employment and Education Status (average number of hours/week Employed or In School or In Vocational Training/Apprenticeship/Internship or Volunteering in the past 12 weeks)

2. Clinical benefits of HoryzonsCa, assessed at baseline and at 12-week follow-up using the following:
2.1. Positive and negative symptoms of psychosis, assessed using the 6-item Positive and Negative Syndrome Scale (PANSS-6)
2.2. Depression, assessed using the 9-item Patient Health Questionnaire (PHQ-9)
2.3. Anxiety, assessed using the 5-item Overall Anxiety Severity and Impairment Scale (OASIS)
2.4. Social support, assessed using the 12-item Multidimensional Scale of Perceived Social Support (MSPSS)
2.5. Loneliness, assessed using the 20-item UCLA Loneliness Scale (Version 3)
2.6. Self-esteem, assessed using the 20-item Self-Esteem Rating Scale Short Form, the 8-item Strengths Knowledge Scale (SKS), and the 14-item Strengths Use Scale (SUS)
2.7. Psychological well-being, assessed using the 14-item Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)

3. The experience and process of adapting and implementing (including moderator training) HoryzonsCa for two age groups (18-35, 36-50) in a bilingual health services context from the perspectives of the research and moderation team, and the acceptability, safety, impact, and implementation of HoryzonsCa from the perspectives of participants (patients) will be assessed qualitatively through the following methods:

3.1. HoryzonsCa Meet-Up and Focus Groups with participants (patients) on an approximate monthly basis during implementation
3.2. HoryzonsCa Moderator Interview at the 12-week follow-up
3.3. Reflective Narratives from the Research and Moderation team at baseline, middle, and end of implementing the intervention
3.4. Field notes taken by team members upon completion of meetings with participants (i.e., the Baseline Interview, HoryzonsCa Orientation Meeting, HoryzonsCa Final Interview)
3.5. Open-ended questions included at the end of the HC-AUSI-Q conducted at the 12-week follow-up (HoryzonsCa Final Interview)

4. Effects of sex, gender, and other sociocultural and demographic factors on the acceptability, safety, impact, implementation, and use of HoryzonsCa, assessed using the Socio-Demographic Questionnaire (including sex, gender, sexual orientation, age, etc.) at baseline, and the Technology Access, Use, and Competency Questionnaire (TAUC-Q) at baseline and at 12-week follow-up

Completion date
30/06/2024

Eligibility

Key inclusion criteria
Participants (Patients)
1. Diagnosis of a psychotic disorder by a clinician, which can include affective psychosis or non-affective psychoses
2. Followed and treated by a clinician of an outpatient clinic at the recruitment setting
3. Considered symptomatically stable and capable of interacting on the online platform and participating in focus groups and semi-structured interviews, as judged by their primary clinicians
5. Aged 18 years or older
6. Complete a screening for suicidal risk, assessed using the Ask Suicide-Screening Questions (ASQ) Toolkit (must indicate no to any of the questions 1 to 3, which assess for recent suicidal ideation)
7. Able to nominate an emergency contact to be eligible for the study

Participants (Moderators and Other Team Members)
Team members aged 18 years or older who have contributed to the adaptation, implementation, or evaluation of the intervention (e.g., clinical moderators, peer moderators, research assistants).

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

Participants (Patients)
1. Intellectual disability
2. Hospitalization at the time of recruitment
3. Inability to speak or read English or French
4. Individuals diagnosed with Antisocial personality disorder and/or Borderline personality disorder

Date of first enrolment
22/03/2021

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Canada

Study participating centre
Douglas Mental Health University Institute
6875 Blvd LaSalle
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Sponsor information

Organisation
Douglas Mental Health University Institute

ROR
https://ror.org/05dk2r620

Organisation
Centre Hospitalier de l'Université de Montréal

ROR
https://ror.org/0410a8y51

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to protection of participants' identity and the confidentiality of the information gathered during this study

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/10/2024	08/10/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes