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Online social therapy to support recovery in youth receiving mental health services

Submission date
09/10/2018

Recruitment status
No longer recruiting

Registration date
01/11/2018

Overall study status
Completed

Last Edited
16/06/2023

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Psychosis is a mental health issue that consists of symptoms such as hallucinations, delusions, disorganized thoughts and behaviours. Psychosis is among the most disabling mental health issues affecting young people today. When psychosis is untreated, it can often lead to significant difficulties in terms of functioning at home and in the community. We now have treatments available for psychosis that include medication, and psychological and social therapies. However, youth face multiple barriers in accessing these psychological and social therapies. New approaches that are accessible and engaging are needed to support recovery from psychosis in the longer-term. The objective of this study is to assess whether it is feasible and acceptable to youth to use a web-based social therapy to sustain recovery and prevent relapses in youth that are receiving treatment for psychosis.

Who can participate?
Adults with a psychotic disorder who are receiving specialised services for first-episode psychosis

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 Horyzons-Canada). While using Horyzons-Canada, participants will be able to access information and educational activities to support their recovery and well-being. Participants will also be able to communicate with clinicians, peers, and a peer support worker through the website. Participants will be invited to an initial interview to obtain baseline information about their mental health and well-being and will be introduced to the website before being able to use it at their convenience. After approximately 1 month of accessing the website, participants will be invited to participate at a focus group meeting with other participants. At the end of 8 weeks of having access to the intervention, participants will be invited to an exit Interview where they will be asked questions asked about their mental health and well-being as well as their experiences and perspectives on the website.

What are the possible benefits and risks of participating?
There may be a personal benefit from participating in this research project, 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 (including travel time), 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 online platform. 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 platform or the focus group discussion outside these contexts.

Where is the study run from?
Prevention and Early Intervention Program for Psychoses at the Douglas Mental Health University Institute, Montreal (Canada)

When is the study starting and how long is it expected to run for?
June 2017 to October 2019

Who is funding the study?
1. NARSAD Brain and Behaviour Research Foundation (USA)
2. Quebec Health Research Funding Agency (FRQS) (Canada)
3. Canada Research Chairs Program (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HCA-P2

Study information

Scientific Title
eHealth intervention to promote recovery and prevent relapses in youth receiving services for first-episode psychosis: pilot study evaluating the acceptability, safety, and potential benefits of Horyzons-Canada

Acronym
HoryzonsCa Pilot Study

Study objectives
Primary hypothesis:
Horyzons will be acceptable to patients based on quantitative and qualitative data obtained through:
1. A semi-structured, interviewer-administered questionnaire (HC-AUSI-Q) consisting of open and closed questions on general experience, perceived usefulness (helpfulness), ease of use
2. Website usage analytics (e.g., frequency of logins)

Secondary hypotheses:
1. Horyzons will be safe, defined as:
1.1. No adverse events, reports or incidents (e.g., hospitalization, suicidal ideation, disclosure to treatment team regarding harm) in relation to use of the online system from baseline assessment to follow-up
1.2. 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 determine safety through qualitatively assessing perceptions of the Horyzons platform (e.g., experiences, concerns).
2. Participants using the Horyzons platform will show improvement or no deterioration on the Clinical Global Impression Scale and on measures related to social functioning, social support, and depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Douglas Mental Health University Institute Research Ethics Board, 11/04/2018, #IUSMD 17-54

Study design
Interventional single-centre single-group pre-post concurrent mixed-methods non-randomised uncontrolled study

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
First-episode psychosis

Interventions
The intervention consists of access to a Web-based portal that includes interactive strengths-based psychosocial interventions (based on positive psychology, CBT for coping and mindfulness, and psychoeducation), peer-to-peer Web-based social networking, as well as clinical and peer moderation to provide guidance and ensure safety. The clinical and peer moderation is informed by self-determination theory and supportive accountability to enhance engagement with the Web-based intervention and motivation in social and psychological functioning. The web-based platform was originally developed in Australia (Horyzons) and has been adapted for use in Canada (HoryzonsCA).
The intervention will be studied using a single-group, mixed-methods, pre-post design. A total of 20 to 25 participants will be recruited into the study and will be provided with access to the website intervention, which is mainly a User-Driven system. This means that there is no minimum requirement for using the website and participants can use whichever parts of the system they choose. Expert moderators will help users make the most of the system and encourage a positive, supportive and safe experience. To support engagement with Horyzons, moderation will be informed by self-determination theory (SDT) which is concerned with supporting our natural or intrinsic tendencies to behave in effective and healthy ways.
Upon consenting to participate in the study, participants will be invited to an initial interview to obtain baseline information about their mental health and well-being and will be introduced to the website before being able to use it at their convenience. After approximately 1 month of accessing the website, participants will be invited to participate in a focus group meeting with other participants. At the end of 8 weeks of having access to the intervention, participants will be invited to an exit Interview where they will be asked questions asked about their mental health and well-being as well as their experiences and perspectives of the website. The follow-up duration, for the purpose of the pilot study, is thus 8 weeks. Participants will be recruited and given access to the website in waves; at a rate of approximately 3 to 5 participants per week until the total sample (20 to 25) has been obtained. After completing the 8 week follow-up, participants will still have access to the website. However, once the target sample has been obtained, and all follow-up data has been collected, participant access to the website will be removed so that analysis can be completed.

Intervention Type
Behavioural

Primary outcome measure

Acceptability (perceived ease of use and perceived usefulness), assessed by the following:
1. Horyzons-Canada 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 baseline (initial interview and orientation meeting) and at the 8 week follow-up (Horyzons exit interview)
2. Website usage analytics, in terms of frequency, duration and patterns of use over the study duration

Secondary outcome measures
1. Safety, assessed using:
1.1. Specific questions in the HC-AUSI-Q examining users views and experience on Horyzons-Canada. In addition, any incidents and adverse events in relation to use of the online system will be carefully monitored and quantified. This will be assessed at the 8 week follow-up.
1.2. Semi-structured interviews (assessed at the 8 week follow-up) and focus group discussion (qualitative data) (assessed at 4 week follow-up).
2. Social functioning, measured at the baseline and 8 week follow-up using the following:
2.1. Social and Occupational Functioning Assessment Scale (SOFAS)
2.2. Personal and Social Performance Scale (PSP)
3. Global improvement and therapeutic response, assessed using the Clinical Global Impression (CGI) at the baseline and 8 week follow-up
4. The following will be assessed at baseline and 8 week follow-up:
4.1. Positive and negative symptoms, depression, anxiety, stress, suicidal ideations, assessed using the Brief Psychiatric Rating Scale (BPRS)
4.2. Positive symptoms, assessed using the Scale for the Assessment of Positive Symptoms (SAPS)
4.3. Social support, assessed using the Multidimensional Scale of Perceived Social Support (MSPSS)
4.4. Negative symptoms, assessed using the Scale for the Assessment of negative symptoms (SANS)
4.5. Self-esteem, assessed using the Self-Esteem Rating Scale (SES)
4.6. Strengths, assessed using the Strengths Use Scale (SUS)
4.7. Depression, assessed using the Calgary Depression Scale (CDS)
5. Access and use of technology, assessed using the Access and Use of Technology Questionnaire at the baseline
6. Impact of the intervention, assessed qualitatively through focus group discussion at the 4 week follow-up and through semi-structured interviews at the 8 week follow-up

Overall study start date
01/06/2017

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. Diagnosis of a psychotic disorder by a clinician, which can include affective psychosis or non-affective psychoses
2. Receiving specialized services for first-episode psychosis
3. Considered symptomatically stable,as judged by their primary clinicians

4. Capable of interacting on the online platform and participating in focus groups and semi-structured interviews, as judged by their primary clinicians
5. 18 years of age or older
6. Low or at most moderate suicidal risk for the month preceding study entry
7. Able to nominate an emergency contact to be eligible for the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 to 25

Total final enrolment
23

Key exclusion criteria
1. Intellectual disability
2. Hospitalization at the time of recruitment
3. Inability to speak or read English
4. Individuals diagnosed with antisocial personality disorder and/or borderline personality disorder
5. Individuals in the acute phase of mania or psychosis

Date of first enrolment
17/09/2018

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
Canada

Study participating centre
Douglas Mental Health University Institute
6875 Blvd LaSalle
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Canada
H4H1R3

Sponsor information

Organisation
Douglas Mental Health University Institute

Sponsor details
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Sponsor type
Research organisation

ROR
https://ror.org/05dk2r620

Funder(s)

Funder type
Government

Funder Name
Brain and Behavior Research Foundation

Alternative Name(s)
Brain & Behavior Research Foundation, The Brain & Behavior Research Foundation, Brain & Behavior Research FDN, The Brain and Behavior Research Foundation, BBRFoundation, National Alliance for Research on Schizophrenia & Depression, NATIONAL ALLIANCE FOR RESEARCH ON SCHIZOPHRENIA AND DEPRESSION, National Alliance for Research on Schizophrenia and Depression, Inc., BBRF, NARSAD

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
Fonds de Recherche du Québec - Santé

Alternative Name(s)
Fonds de la recherche en sante du Quebec, FRQS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Funder Name
Canada Research Chairs

Alternative Name(s)
Chaires de recherche du Canada

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Planned publications in peer-reviewed journals and presentations at peer-reviewed scientific conferences.

Intention to publish date
30/06/2023

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 the 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		07/12/2021	09/12/2021	Yes	No
Results article		07/04/2023	16/06/2023	Yes	No