

ACCESS Open Minds / ACCESS Esprits ouverts

Submission date 16/12/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/02/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/11/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Youth in most Canadian communities have a difficult time getting the right mental health care. It can be difficult to know where and how to seek care, the wait can be long and the path to help can be complex. Services rarely fit their unique needs. It has been shown however that the sooner a mental health problem is identified and treated, the better a young person's future is likely to be. The ACCESS OM research project is using best practices from around the world to develop, test, and evaluate a new model of care at different sites representing the diversity of settings across Canada. The intention is to give youth aged 11 to 25 years faster access to youth-friendly mental health services designed with input from them and their families/carers. ACCESS OM aims to evaluate youth's experience with this new model of care. Each ACCESS OM site's current services are being transformed to meet the new 5 ACCESS OM objectives:

1. Early identification: Increasing awareness of mental health problems and of the ACCESS OM service to reach more youth in need, earlier
2. Rapid access: Offering youth an initial assessment within 72 hours of help-seeking, for any type of mental health problem, without a formal referral
3. Appropriate care: Youth receive services that meet their needs and preferences within 30 days
4. Continuity of care: Services are integrated for youth aged 11 to 25, and any transitions in service provider are based on youth's needs
5. Youth and family engagement: Youth and their families/carers are involved in all aspects of the research project and service delivery. They are treated as experts in their own experience.

Youth and their families/carers are therefore involved in every aspect of ACCESS OM, from the design and evaluation of services, to the creation of content for the website. The aim of this study is to look at the long-term effects of ACCESS Open Mind's service transformation on youth's experiences with mental health treatment.

Who can participate?

People aged between 11 and 25 who have mental health problems and are seeking/have been referred to mental health services at a participating site, and their family members or carers.

What does the study involve?

Each ACCESS OM site transforms their services at different points in time to meet the 5 ACCESS OM objectives. Within each ACCESS OM site, wait times and youth outcomes are compared both

before and after services have been transformed. Youth with mental health problems can directly contact ACCESS OM to get help. They are offered an appointment within 72 hours to assess their needs. At the first meeting, the youth and the ACCESS Clinician answers questions together to see what type of care the youth needs. If the youth wants, their families/carers can be included in the process. Without requiring a formal diagnosis, the ACCESS Clinician helps the youth access the right care. The length of care provided depends on what the youth needs. While youth are receiving care, the ACCESS Clinician follows up with them regularly to see how they are doing at months 1, 3, 6, 9, 12 and 24.

What are the possible benefits and risks of participating?

There are no direct benefits of participating as all patients (whether they take part in the study or not) benefit from accessing services at the ACCESS OM sites which could help improve their mental health. There is a small risk that some participants may experience some emotional discomfort when answering questions (such as about their past experiences), however they do not need to answer questions they do not feel comfortable answering.

Where is the study run from?

The study is being run from the Douglas Hospital Research Centre in Montréal and takes place in 12 mental health services (Canada).

When is study starting and how long is it expected to run for?

April 2014 to March 2021

Who is funding the study?

1. Graham Boeckh Foundation (Canada)
2. Canadian Institutes of Health Research (Canada)

Who is the main contact?

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Study website

<http://accessopenminds.ca/>

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MHB-135810

Study information

Scientific Title

Developing, implementing and evaluating a model for youth mental health service transformation in Canada: ACCESS Open Minds

Acronym

ACCESS OM

Study objectives

Primary Hypotheses

As a result of ACCESS Open Mind's service transformation, over time:

1. There will be a significant increase in the number of youth being referred for mental health services, accounting for variations in the population of youth in the catchment areas served by the sites
2. The number of help-seeking youth being offered an initial assessment by a trained clinician within 72 hours will increase
3. There will be a higher proportion of youth with serious mental health problems whose wait times for appropriate care/interventions meet modified Canadian Psychiatric Association benchmarks (less than 30 days except in urgent cases)

Secondary Hypotheses

As a result of ACCESS Open Mind's service transformation, over time:

1. Youth will have had to make fewer help-seeking contacts before accessing appropriate care

2. Youth receiving services at ACCESS will have better clinical, functional and subjective outcomes
3. Satisfaction with mental health services will be higher amongst youth and their families/carers

Ethics approval required

Old ethics approval format

Ethics approval(s)

Douglas Institute Research Ethics Board, 03/11/2015, ref: #15-21

Study design

Community-led stepped wedge cluster randomised trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Other

Participant information sheet**Health condition(s) or problem(s) studied**

Youth mental health care

Interventions

Each of the 12 ACCESS OM site are transforming their services to meet the new 5 ACCESS OM objectives:

1. Early Identification, to ensure that more youth are referred sooner, through activities such as targeted outreach, community awareness, etc.
2. Rapid and Engaging Access, to offer youth, and those seeking help on their behalf, access to an initial evaluation within 72 hours in a stigma-reducing environment. Key strategies include the addition of a trained clinician (Access Clinician) who serve as a single point of contact and that can be directly accessed by youth in need or those acting on their behalf; who respond in less than 72 hours; who can offer an initial evaluation irrespective of type/severity of mental health problem; and who can, in collaboration with youth and their families/carers, link the young person to needs-appropriate services. Other strategies for rapid access are inclusion of multiple portals for accessing care, including direct walk-in access; and elimination of any referral or administrative requirements.
3. Appropriate care, to offer youth evidence-informed interventions staged by phase of illness and level of care needed (as opposed to only diagnosis-based), with a focus on reducing wait times to meet modified Canadian Psychiatric Association benchmarks (less than 30 days except in urgent cases). Care is provided in strengths-based, youth-friendly, engaging, rights-respecting, non-stigmatizing, and recovery-oriented environments.
4. Continuity of care, to ensure youth are supported through any transitions between services and that these transitions are based on needs and not age. Collaboration between services,

stakeholders, sectors, and disciplines are fostered to facilitate seamless transitions for service users.

5. Youth and Family/Carers participation, to ensure their active engagement in all aspects of this project. As Canadian Institutes of Health Research's (CIHR) first Strategy for Patient-Oriented Research (SPOR) initiative, the vision is to ensure that youth and their families/carers with lived experience contribute to the values and objectives associated with this transformed system of youth mental health care. This occurs both at the service level, and at the individual-level, as valued decision makers in the care they are offered.

Of the 12 ACCESS Open Minds (OM) sites across Canada, six of the sites are randomly assigned to either Wave 1, Wave 2 or Wave 3 which dictates when their service is transformed.

Randomisation is stratified by population size. As per stratified randomisation methods, a separate block is created for the co-variate of Indigenous sites and a simple randomisation involving all blocks is performed with members of each site present. Each ACCESS OM site initiates the same service transformation (receipt of training and launching the transformed services) at different time points, as determined by the Wave in which they are randomly allocated to. Wave 1 sites transform their service first, Wave 2 sites follow six months later and Wave 3 changes a further six months after Wave 2. The remaining six sites that are not included in the randomisation process serve as special demonstration sites where the same service transformation occurs at some point in the future but with less of a demanding minimum evaluation protocol.

Participants with mental health problems directly contact ACCESS OM sites to receive help. The participants receive mental health care provided by an ACCESS Clinician, which is a novel position within each ACCESS OM site. The ACCESS Clinician ensures youth receive the offer of an initial evaluation without the need of a formal referral (which is standard) and within 72 hours of the request. The initial evaluation is conducted by the trained ACCESS Clinician to assess the youth's self-rated psychological distress (Kessler-10 Psychological Distress Scale (K-10)), functioning (Social and Occupational Functioning Assessment Scale (SOFAS)) and symptoms (Clinical Global Impressions – Youth Mental Health (CGI-YMH)) and is not based upon diagnosis. The ACCESS Clinician refers youth to appropriate care based on their needs and preferences within 30 days. Families/carers can be included in the process if the participant requests it. The duration of the mental health services received is based on the youth's needs and the ACCESS Clinician continue to support the youth through any service transitions by conducting regular evaluations to assess youth's clinical, subjective and functional outcomes at baseline, and 1,3,6,9,12, and 24 months.

Intervention Type

Mixed

Primary outcome measure

1. Number of referrals from youth (or those seeking help on behalf of youth) at ACCESS OM sites is measured by comparing referral rates before and after transformation using retrospective institutional data and post-transformation data via an online data collection system (DACIMA)
2. Number of youth who receive the offer of an initial evaluation within 72 hours of referral is measured by comparing retrospective data with data collected using the Services and Interventions Documentation Form created by ACCESS OM at baseline and documents the timeline of the youth's referral and intake as well as communication between the service user and clinician
3. Proportion of youth with a serious mental illness receiving appropriate care in less than 30 days (except for urgent cases) is measured by comparing retrospective data with data collected

using the Services and Interventions Documentation Form created by ACCESS OM, which is completed at baseline, 1, 3, 6, 9, 12 and 24 months

Secondary outcome measures

1. Number of help-seeking contacts before accessing appropriate mental health care for youth with serious mental illness is measured using institutional data at baseline
2. Levels of satisfaction among youth and their families/carers is measured using the Ontario Perception of Care Tool for Mental Health and Addictions (OPOC-MHA), at 1, 3, 6, 9, 12, and 24 months
3. Clinical, functional and subjective outcomes of youth receiving services at ACCESS OM sites is primarily measured using the Clinical Global Impressions - Youth Mental Health (CGI-YMH), the Social and Occupational Functioning Assessment Scale (SOFAS), Kessler-10 Psychological Distress Scale (K-10), at baseline, 1, 3, 6, 9, 12 and 24 months

Overall study start date

01/04/2014

Completion date

31/03/2021

Eligibility

Key inclusion criteria

Youth:

1. Aged between 11 and 25
2. Seeking, or being referred to, mental health services at one of the twelve sites

Carers:

Family members or identified caregivers of participating youths.

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

The estimated number of participants throughout the life of the project at our 12 participating sites is 13,760. ACCESS OM is not a traditional RCT as the focus of the study is on transforming existing community-based mental health services so that youth receive care that is timely, appropriate, and engaging. There is no specific target number of participants, as one of the objectives is to reduce the unmet need for mental health services at each of the ACCESS OM participating sites. There are 12 sites, each of which serves unique populations, ranging from a remote Inuit community of 400 to a densely-populated catchment area in Montreal of over 100,000 residents. Part of the service transformation model also involves increasing early identification activities so that more youth in need are identified earlier. This will ultimately increase the number of youth who present to services. As youth will not be turned away from

receiving services, and there are few exclusion criteria, it is difficult to project the total number of youth that will present to all ACCESS OM sites throughout the five year project, and how many of those youth will consent to research.

Key exclusion criteria

Youth:

1. Outside the age range of the project (under 11 or over 25)
2. Intellectual disability (IQ<70)
3. History of organic brain damage

Date of first enrolment

12/09/2016

Date of final enrolment

30/09/2020

Locations

Countries of recruitment

Canada

Study participating centre

Eskasoni First Nation

30 Medicine Trail

Eskasoni

Canada

B1W 1B3

Study participating centre

Chatham-Kent

335 King Street West

Chatham

Canada

N7M 1G2

Study participating centre

Edmonton

10211 105 St NW

Edmonton

Canada

T5J 1E3

Study participating centre

Parc-Extension

7085 Hutchison
Montreal
Canada
H3N 1Y9

Study participating centre**Dorval-Lachine-Lasalle**

1900 Notre-Dame Street
Lachine
Canada
H8S 2G2

Study participating centre**Mistissini**

187 Main Street
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Canada
G0W 1C0

Study participating centre**Réseau d'Intervention de Proximité Auprès des Jeunes (RIPAJ-Montréal/Homeless Youth Network)**

1664 Ontario Street East
Montreal
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H2L 1S7

Study participating centre**Puvirnituk**

Inuulitsivik Health & Social Services Centre
Puvirnituk
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J0M 1P0

Study participating centre**University of Alberta**

Office of the Dean of Students, 5-02 Students' Union Building, University of Alberta
Edmonton
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Study participating centre
Sturgeon Lake First Nation
726 Education Road
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Study participating centre
Ulukhaktok
Ulukhaktok Community Corporation
Ulukhaktok
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X0E 0S0

Study participating centre
Centre de Bénévolat de la Péninsule Acadienne
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E1W 1A5

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Elsipogtog Health & Wellness Centre
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P.E.E.R. Saint John
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Sponsor information

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Canadian Institutes of Health Research

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Sponsor type

Government

Website

<http://www.cihr-irsc.gc.ca/e/193.html>

ROR

<https://ror.org/01gavpb45>

Funder(s)**Funder type**

Charity

Funder Name

Graham Boeckh Foundation

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, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Publication and dissemination plan

Planned publications in high-impact peer reviewed journals.

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/09/2019	18/05/2020	Yes	No
Other publications	Demographic and clinical characteristics	19/11/2021	22/11/2021	Yes	No