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Is psychotherapy delivered in videoconference as effective as in face to face for GAD?

Submission date
30/10/2014

Recruitment status
No longer recruiting

Registration date
28/11/2014

Overall study status
Completed

Last Edited
13/10/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Everyone experiences worry and anxiety now and then, but for some people it's difficult to control these feelings. These people may develop a condition called generalized anxiety disorder (GAD). People who have GAD feel anxious most days, which can lead to a number of debilitating mental and physical symptoms. These include feeling irritable and unable to concentrate, tiredness, feeling dizzy, heart palpitations, muscle tension, feeling sick, headaches and insomnia. Unfortunately, most GAD patients do not receive treatments that have been proven to work for the condition, especially when it comes to psychotherapy. Previous studies have looked at how well telepsychotherapy (i.e., psychotherapy delivered via videoconference systems) works at a treatment for panic disorder, post traumatic stress disorder, obsessive-compulsive disorder, major depression and eating disorders, but no study has addressed this question with GAD. Research has shown that it's possible to develop a strong and successful bond (working therapeutic alliance) between patients and their therapist in telepsychotherapy, but again this hasn't been looked at in relation to people with GAD. And, although patients are known to be generally accepting of telepsychotherapy, the costs and time involved in getting to a treatment site to receive CBT (cognitive behaviour therapy) by trained mental health professionals has not been investigated. Here, we want to use statistics to investigate whether telepsychotherapy is as good as traditional face-to-face CBT in treating GAD. We also compare the costs involved in providing CBT for GAD in five clinics across the province of Quebec.

Who can participate?
French speaking adults aged 18 to 75 that have been diagnosed with GAD.

What does the study involve?
Participants are randomly assigned to receive either face-to-face CBT at their local clinic or in videoconference. For those assigned to the videoconference condition, the location of the remote site (i.e., the other city where the therapist will be located) is also assigned randomly. Diagnostic interviews and questionnaires are completed before and after the 15-week treatment, as well as at the 6- and 12-month follow-up. Working therapeutic alliance and other potential ways of assessing the success of the treatment is measured throughout the study.

What are the possible benefits and risks of participating?
Participants will receive free psychotherapy for their generalized anxiety disorder. This treatment is the gold standard form of psychotherapy and will provided to all. The only difference is whether it will be given face-to-face or via videoconference. There are no risks, expect those associated with going in psychotherapy: talking about personal issues and dealing with emotions.

Where is the study run from?
Recruitment and therapy are provided in five sites in the province of Quebec, Canada: Gatineau (the lead site), Montréal, Québec, Sherbrooke and Trois-Rivières.

When is the study starting and how long is it expected to run for?
November 2013 to March 2017

Who is funding the study?
Canadian Institutes of Health Research (Canada)

Who is the main contact?
Professor Stéphane Bouchard
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MOP-1259765

Study information

Scientific Title
A non-inferiority randomized control trial comparing cognitive-behavior therapy delivered in videoconference or in face-to-face for adults suffering from generalized anxiety disorder.

Acronym
VC_vs_FF_GAD

Study objectives
1. Cognitive behavior therapy (CBT) will be as effective (i.e., not significantly inferior) as traditional face-to-face when delivered through videoconference.
2. Receiving CBT in videoconference will be less costly than having to come to the clinic to receive CBT in face-to-face.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité dÉthique à la Recherche de lUniversité du Québec en Outaouais, 26/11/2013, ref. UQO-1754

Primary study design
Interventional

Study design
Two arms non-inferiority randomized control trial.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Generalized anxiety disorder

Interventions
After receiving an appropriate diagnosis and completing the ethics procedures, participants will be randomly assigned to one of the following two conditions:

1. CBT delivered in face-to-face: The gold standard treatment developed by Dugas et al. will be applied in weekly sessions where the patient and the therapist are in the same room.
2. CBT delivered in videoconference: The gold standard treatment developed by Dugas et al. will be applied in weekly sessions where the patient is in a room at the local site (i.e. city where the patient attends the treatment) and the therapist is in a different room in the remote site (i.e. a different city, where the therapists delivers the treatment).

For both conditions, the treatments will be similar to what is being used in other research centers, with treatment beginning by a case conceptualization, followed by identification of worry processes, cognitive restructuring of the usefulness of worries, building tolerance to uncertainty with in vivo exposure, building problem solving skills, exposure in imagination to worse fear scenarios, and relapse prevention. The only difference between the two conditions is that patients and therapist may be, or not, in the same room / city. All treatments will last 15 sessions and will be supervised by the principal investigator and the co-investigators. The treatment will be delivered by graduate students experienced in CBT and the treatment of anxiety disorders. A standardized treatment will be conducted for 15 weekly 60-minutes sessions delivered by experienced therapists. Treatment fidelity will be enhanced by the use of treatment manuals and weekly supervisions. Adherence to the research protocol will be assessed regularly by independent raters who will review videotapes of therapy sessions.

Intervention Type
Behavioural

Primary outcome(s)
Severity of GAD symptoms on the Anxiety Disorders Interview Schedule (ADIS):
The ADIS is a semi-structured interview rating the severity of each symptoms of GAD to provide a global severity rating. It is a common outcome measure in research on GAD. Inter-rater reliability will be assessed and maintained during the entire study. Total score varies between 0 to 8.
The ADIS will be administered at baseline, post-treatment and at the 6- and 12-month follow-ups.

Key secondary outcome(s)
1. Penn-State Worry Questionnaire:
This self-report measures signs of GAD and the tendency to worry. The subject must indicate to which degree he or she agrees with 16 assertions typical people suffering from GAD. All items are rated on a 0 to 5 scale.
2. Worry and Anxiety Questionnaire:
This questionnaire is a self-rating of the severity of DSM-5s GAD symptoms measured by the ADIS. All symptoms are rated on a 0 to 8 scale.
3. Intolerance of Uncertainty:
Participants rate 45 items assessing the core psychological mechanism of GAD, namely intolerance of uncertainty. This fear of uncertainty is the reason motivating patients to engage in ruminations and worries in order to anticipate and protect themselves from dreaded consequences of daily stressors. All items are rated on a 0 to 5 scale.
All outcomes will be assessed at baseline, post-treatment and at the 6- and 12-month follow-ups.

Completion date
01/03/2017

Eligibility

Key inclusion criteria
1. Ambulatory man and woman
2. At least 18 years old and at most 75 years old
3. French speaking
4. Receiving a principal diagnosis of GAD based on DSM-5 diagnostic criteria. Assessed with asemi-structured diagnostic interview (ADIS)
5. If currently taking medication for GAD, pharmacotherapy must me stabilized (same type and dosage) for at least six months and the GAD remained stable and uncured (i.e. still meeting the diagnostic criteria). Note that there is no perfect solution to the problem of medication since most severe cases already receive Selective Serotonin Reuptake Inhibitor (SSRI) from their doctors when they seek psychological treatments (thus, recruiting non-medicated participants would threaten the feasibility of the study and could lead to the selection of less severe cases) and stopping medication would induce other methodological problems (e.g., withdrawal symptoms, artificial peak of severity at pre-treatment, ethical issues)

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
46

Key exclusion criteria
1. Having a principal diagnosis other than GAD
2. Currently suffering from a severe organic disease, dementia, mental retardation, schizophrenia, amnesia, substance abuse, borderline personality disorder, psychosis or bipolar disorder
3. GAD being secondary to a medical condition
4. Active suicidal ideations
5. Starting a new medication or changing actual medication

Date of first enrolment
26/11/2013

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
Canada

Study participating centre
University of Quebec at Outaouais (Université du Québec en Outaouais)
Gatineau
Canada
J8X3X7

Sponsor information

Organisation
University of Quebec at Outaouais (Université du Québec en Outaouais (UQO)) (Canada)

ROR
https://ror.org/011pqxa69

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (Canada) (Project # 2012-09-MOP-285534-PB1-CFEF-21237, 125976).

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), 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

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/03/2021	16/03/2021	Yes	No
Results article		07/10/2022	13/10/2022	Yes	No