

Why is psychotherapy delivered in videoconference as effective as in face to face in the treatment of panic disorder with agoraphobia?"

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Registration date 10/12/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/09/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Panic disorder with agoraphobia (PDA) is a common, severe mental disorder characterized by recurrent panic attacks (in which symptoms can include nausea, sweating, trembling and palpitations) and a fear of being in a situation where escape may be difficult or help may not be available in case they have a panic attack. PDA can be treated with a form of psychotherapy called cognitive behaviour therapy (CBT) where patients have to progressively confront their fear in a procedure called exposure. Unfortunately, most PDA 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 PDA. 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 PDA. Here, we want to use statistics to investigate whether telepsychotherapy is as good as traditional face-to-face CBT in treating PDA

Who can participate?

French speaking Adults aged 18 to 75 that have been diagnosed with PDA.

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 panic disorder. This treatment is the gold standard form of psychotherapy and will be provided to all. The only difference is whether it will be given face-to-face or via videoconference. There are no risks, except 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, Shawville, Maniwaki and Fort-Coulonge.

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

August 2002 to May 2006

Who is funding the study?

Canadian Institutes of Health Research (Canada)

Who is the main contact?

Professor Stéphane Bouchard

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Study website

<http://w3.uqo.ca/cyberpsy>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Factors associated with acceptability and predictors of outcome for a cognitive-behavior therapy of panic disorder with agoraphobia delivered in videoconference

Acronym

VC_vs_FF_PDA

Study objectives

H1: Psychotherapy will be as effective when delivered in videoconference as in face-to-face.

H2: Motivation towards therapy, strength of the therapeutic bond with the therapist and feeling of presence will be significant predictors of treatment outcome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Comité d'Éthique à la Recherche de l'Université du Québec en Outaouais, 06/08/2002, ref. UQO-156
2. Centre hospitalier Pierre-Janet, 25/06/2002

Study design

Two arms non-inferiority randomized control trial comparing an active psychological treatment delivered following two modalities (face-to-face or videoconference).

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet [in French].

Health condition(s) or problem(s) studied

Panic Disorder and agoraphobia treated through videoconference

Interventions

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

1. CBT delivered in face-to-face: The gold standard treatment inspired by Barlow & Cerny (1988) and Clark & Salkovskis (1987) manuals was applied in weekly sessions where the patient and the therapist are in the same room.
2. CBT delivered in videoconference: The gold standard treatment inspired by Barlow & Cerny (1988) and Clark & Salkovskis (1987) manuals was applied in weekly sessions where the patient was in a room at the local site (i.e. city where the patient attends the treatment) and the therapist was in a different room in the remote site (i.e. a different city, where the therapists delivers the treatment).

For both conditions, the treatments were similar to what is being used in other research centers and was delivered according to a standardized treatment manuals beginning by a case conceptualization, information on panic disorder, appraisal and avoidance of physiological sensations; cognitive restructuring; exposure (interoceptive and agoraphobic); relapse prevention. A standardized treatment was conducted for 12 weekly 60-minutes sessions delivered by experienced therapists and were supervised by the principal investigator and the co-investigators. Treatment fidelity was enhanced by the use of treatment manuals and weekly supervisions. Adherence to the research protocol was assessed regularly by independent raters who reviewed videotapes of therapy sessions.

Intervention Type

Behavioural

Primary outcome measure

1. Severity of PDA symptoms. The degree of severity of panic disorder and agoraphobia was assessed by the participant with the Panic and Agoraphobia Scale (PAS). The PAS contains 13 items with 0-4-point scales grouped in five subscales: panic attacks (frequency, severity, and duration), avoidance, anticipatory anxiety, disability (family, social, employment), and worries about health. The total score is obtained by summing the item scores.

Secondary outcome measures

Secondary measures (pre-, post-, 6 and 12 month follow-up):

1. Daily diaries: Panic attacks and panic apprehension were recorded in diaries completed during a 4-week self-monitoring period. Subjects were instructed to carry the panic diary with them at all times and were taught to identify and monitor panic attacks.

2. Self-report outcome measures:

- 2.1. The Agoraphobic Cognition Questionnaire
- 2.2. Body Sensation Questionnaire
- 2.3. Mobility Inventory (alone and accompanied versions)
- 2.4. Self-Efficacy to Control a Panic Attack Scale

The first three instruments are standard measures used in outcome studies on PDA, and the last one is a psychometrically sound instrument that has been used successfully in a previous study. Three other measures were used to assess generalization of the results:

3. State-Trait Anxiety Inventory
4. Beck Depression Inventory
5. Sheehan Disability Scale

Self-report measures of clinically relevant aspects of videoconference:

6. The clients perception of the therapeutic alliance between the participant and the therapist was assessed with the Working Alliance Inventory.

Overall study start date

06/08/2002

Completion date

08/05/2006

Eligibility

Key inclusion criteria

1. Ambulatory man and woman
2. At least 18 years old and at most 65 years old
3. French speaking
4. Receiving a principal diagnosis of PDA based on DSM-IV diagnostic criteria. Assessed with a semi-structured diagnostic interview (SCID-I)
5. If currently taking medication for PDA, pharmacotherapy must be stabilized (same type and dosage) for at least three months and the PDA 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

59

Total final enrolment

71

Key exclusion criteria

1. Having a principal diagnosis other than PDA
2. Currently suffering from a severe organic disease, dementia, mental retardation, schizophrenia, amnesia, substance abuse, borderline personality disorder, psychosis or bipolar disorder
3. PDA being secondary to a medical condition

4. Active suicidal ideations
5. Starting a new medication or changing actual medication
6. Receiving another psychotherapy to treat PDA in the last 6 months

Date of first enrolment

06/08/2002

Date of final enrolment

08/05/2006

Locations

Countries of recruitment

Canada

Study participating centre

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

Department of Psychology (Dept. psychologie)

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Sponsor information

Organisation

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Sponsor type

University/education

Website

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ROR

<https://ror.org/011pqxa69>

Funder(s)

Funder type

Government

Funder Name

Canadian Institutes of Health Research (MOP-53366) (Canada)

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

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/08/2020	28/09/2020	Yes	No