The effect of a cognitive behavioural program called Michaels Game on psychotic symptoms

Submission date 06/04/2013	**Recruitment status** No longer recruiting	[ ] Prospectively registered
		[ ] Protocol
Registration date 04/07/2013	**Overall study status** Completed	[ ] Statistical analysis plan
		[X] Results
Last Edited 22/09/2020	**Condition category** Mental and Behavioural Disorders	[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Psychosis is a mental disorder in which thought and emotions are impaired, causing a person to lose touch with reality. Medication is often used to treat people suffering from psychosis, but it is not always effective as patients often do not take their medication. The one-to-one talking therapy, cognitive behavioural therapy (CBT) has been shown to be a particularly effective treatment for psychosis, as it teaches patients to successfully manage their problems by changing their behaviour. "Michael's game" is a card game which has been developed to help therapists and patients become familiar with CBT. Within the game, participants have to help "Michael" to find alternatives to the wrong conclusions that he draws from the situations described on each card. Michael's game can then be used in order to predict how patients will respond to CBT. The aim of this study is to look at whether the use of Michael's game is a feasible option for the treatment of patients with psychosis who are on the waiting list for CBT.

Who can participate?
Adults with a psychotic disorder taking anti-psychotic medication and undergoing treatment as an outpatient.

What does the study involve?
Patients are randomly divided into one of two groups. The first group (control group), continue their normal treatment and are placed on the waiting list for CBT. The second group (intervention group), continue their normal treatment and take part in Michael's game. At the start of the study, all patients are given questionnaires and are interviewed in order to evaluate their medical history and population statistics. These tests are repeated again after three months and then after a further 6 months.

What are the possible benefits and risks of participating?
There is a very low risk to the patients who are participating, as Michael's game is non-invasive and there is no evidence of it being harmful. A potential benefit of being in the intervention group is that it could lead to an improvement in the patients' treatment.

Where is the study run from?
Geneva University Hospitals (Switzerland)

When is the study starting and how long is it expected to run for?
April 2008 to March 2011

Who is funding the study?
Swiss National Science Foundation (Switzerland)

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
Swiss National Science Foundation Grant: 32003B-121038

Study information

Scientific Title
A multicentric randomized controlled study of the effect of a cognitive behavioural program called Michael's Game on psychotic symptoms

Study objectives
Our main hypothesis is that the subjects who will take part in the module Michaels Game will show a greater modification of their attitudes toward the positive psychotic symptomatology (in

terms of anxiety inducing character, degree of preoccupation, conviction, and behaviour disturbances associated with these symptoms) and a better improvement of insight than control subjects on the waiting list.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethic Commission Geneva University Hospitals, 17th October 2008, ref: Protocol No 08-193

Study design
Randomized controlled multicentric blind assessment study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (in French)

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

Interventions
Treatment as usual + Michaels Game vs. treatment as usual + waiting list

Cognitive Therapy (psychotherapy)
Group Format
Game Format

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Peters Delusion Inventors (PDI-21) - A 21-item scale that assesses the degree of expression of psychotic beliefs. Three dimensions of delusional beliefs are investigated: the degrees of preoccupation, of conviction, and of related anxiety.
This scale has notably been used to investigate the benefits of cognitive and behavioural

therapies of psychoses (Garety et al., 1997 and Kuipers et al., 1997 and 1998).
Measured at baseline, Months 3 (post Michael's Game Treatment) and six months later

Secondary outcome measures
All measured at baseline, Months 3 (post Michael's Game Treatment) and six months later
1. The BPRS (Brief psychiatry rating scale) (Overall et al. 1961) An 18-item scale that measures the severity of the symptoms in functional psychoses. Comes in the form of a semi-structured interview.
2. The BCIS (Beck Cognitive Insight Scale (Beck et al. 2004) A 15-item scale that assesses self-reflectiveness (insight and desire to recognize its fallibility) and self-certainty (certainty regarding patients beliefs and judgement) regarding the interpretation patients have for their experience.This self-report questionnaire enables the research units to access the patients ability to evaluate their abnormal experiences and their erroneous inferences.
3. PDI 21 Peters and al. Delusions Inventory Peters et al. (1999) A 21-item scale that assesses the degree of expression of psychotic beliefs. Three dimensions of delusional beliefs are investigated: the degrees of preoccupation, of conviction, and of related anxiety. This scale has notably been used to investigate the benefits of cognitive and behavioural therapies of psychoses (Garety et al., 1997 and Kuipers et al., 1997 and 1998)
4. The GAF [Global Assessment of Functioning] (DSM-IV) A scale that allows for an evaluation of the level of global functioning (psychological, social, and professional) of a person by means of a unique score. It can be divided into ten levels of functioning. The description of each level has two components: the first one corresponds to the severity of the symptoms, and the second one to functioning. This scale has good psychometric qualities and is a tool frequently used in clinical routine.
5. The SOFAS [Social and Occupational Functioning Assessment Scale] (DSM-IV) In contrast with the GAF, the SOFAS focuses on the individual's level of social and occupational functioning while excluding severity of symptoms.
6. The MADS (Maudsley Assessment of Delusions Schedule) (Wessely et al. 1993) This scale has particularly been created to bring to the fore links between the actions resulting from the main belief and its phenomenological qualities. It is composed of 8 subscales: conviction, beliefs, emotion, action, idiosyncrasy, preoccupation, systematization, insight. It consists of a standardized semi-structured interview.
7. CSSRI-EU - Client Socio-Demographic and Service Receipt Inventory (Chisholm et al., 2000) This tool is made up of five sections consisting of structured interviews to assess: socio-demographic, normal living conditions, employment and income, service receipt, medication profile

Overall study start date
01/04/2008

Completion date
31/03/2011

Eligibility

Key inclusion criteria
1. Psychotic disorder according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV), diagnoses are established by experienced clinicians (from the psychiatric services teams)
2. Treatment in an outpatient setting, day hospital or rehabilitation unit
3. Age18-65 years
4. Positive psychotic symptoms defined by: a score of ≥ 3 on at least 2 of the items of the

positive symptoms on the Brief psychiatry rating scale (BPRS)
5. Patients informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
166

Key exclusion criteria
1. Evidence of organic brain disease, clinically significant concurrent medical illness or learning disability
2. Conceptual disorganization score on the BPRS of >5
3. Prior participation in the "Michaels Game" program
4. Cognitive behavioral therapy (CBT) of psychotic symptoms at the time of inclusion

Date of first enrolment
01/04/2008

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
Italy

Switzerland

Study participating centre
Geneva University Hospitals
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Sponsor information

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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Government

Funder Name
Swiss National Science Foundation (Switzerland) Grant: 32003B-121038

Results and Publications

Publication and dissemination plan

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	28/04/2015		Yes	No
[Results article](#)	results	01/12/2019	22/09/2020	Yes	No