Psychological treatments for problem gambling reseach Study (PROGRESS)

Submission date	Recruitment status	[X] Prospectively registered		
18/09/2012	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/10/2012	Completed	Results		
Last Edited	Condition category	Individual participant data		
26/11/2015	Mental and Behavioural Disorders	Record updated in last year		

Plain English summary of protocol

Background and study aims

The DSM IV (American Psychiatric Association, 2000) defines pathological gambling as 'Persistent and recurrent maladaptive gambling behavior' with at least 5 out of 10 associated criteria required to be attained in order to merit the diagnosis. In the US, problem gambling is often considered to be a sub-clinical form of pathological gambling but in many other jurisdictions, the term 'problem gambling' (PG) is used to encompass all people with a significant gambling problem. Problem gambling often has important health and social consequences for those who have it. Divorce rates are high, family violence and relationship problems generally are more common. Bankruptcy rates and participation in criminal activity related to money are also higher amongst this group than in the general community. A recent Cochrane review of the problem gambling treatment literature has found that psychological treatments, such as cognitive behaviour therapy and motivational interviewing, could be helpful in reducing problem gambling. These reviews also identified the current gaps in knowledge about effective treatments for problem gambling and have shown that more research is required to determine which treatment is most effective, and which one works best for whom. The purpose of this study is to investigate the effectiveness of psychological treatments for problem gambling and to determine if the effects can be sustained over time. It will also examine if different types of people respond better to certain types of psychological treatment.

Who can participate?

This study aims to recruit participants aged 18 years and above, wish to receive treatment for their gambling problem and can communicate in the English language. Individuals that are unable to provide informed consent, are at risk of self-harm or are currently receiving other treatments for their gambling problem or have received such treatment in the past 12 months from a counsellor or therapist are not able to participate in this study.

What does the study involve?

Participants will be randomly allocated to one of four treatment arms including cognitive-behavioural therapy, behavioural therapy, motivational interviewing and client-centred therapy. Participants will receive six individual sessions of face-to-face treatment with a psychologist.

Information relating to the participants gambling activities, psychological profile and wellbeing will be collected immediately before and after treatment and at 6, 12, 18 and 24 months after the completion of treatment using telephone interviews.

What are the possible benefits and risks of participating?

Participants will receive free treatment for their gambling problems. The information obtained from this study may benefit people seeking help for their gambling problems in the future by informing treatment providers of effective interventions. The main risk involved in taking part in this study is possible distress associated with receiving any psychological intervention for a disorder of this kind.

Where is the study run from?

This study is being conducted by the Problem Gambling Research and Treatment Centre, a joint initiative of Monash University and the University of Melbourne. The study is led by Monash University Problem Gambling Research and Treatment Centre.

When is the study starting and how long is it expected to run for? The study has commenced in August 2012 and recruitment will occur until June 2013. Post intervention data will conclude in June 2015.

Who is funding the study? Funding has been provided by the Victorian Department of Justice.

Who is the main contact? Professor Shane Thomas shane.thomas@monash.edu

Study website

http://www.med.monash.edu.au/pgstudy

Contact information

Type(s)

Scientific

Contact name

Prof Shane Thomas

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised controlled trial to determine effective psychological treatments for problem gambling

Acronym

PROGRESS

Study objectives

To determine the effectiveness of manualised cognitive-behavioural therapy, behavioural therapy, client-centred therapy and motivational interviewing interventions in reducing gambling activity and gambling symptom severity immediately after treatment and up to 2 years follow-up.

Updated 26/08/2015:

Overall trial duration has been updated from 01/08/2012 - 01/06/2015 to 01/01/2013 - 01/12 /2015. Overall recruitment duration has been updated from 01/08/2012 - 01/06/2015 to 01/01 /2013 - 01/02/2014.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Victorian Department of Justice Human Research Ethics Committee, 07/12/2011, ref: CF/11/22687
- 2. Monash University Human Research Ethics Committee, 20/12/2011, ref: CF11/3707 2011001954
- 3. University of Melbourne Central Human Research Ethics Committee, 06/02/2012, ref: 1237304

Study design

Parallel-group randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Patient information material can be found at http://www.med.monash.edu.au/sphc/pgrtc/rct/index.html

Health condition(s) or problem(s) studied

Pathological and problem gambling

Interventions

Participants will be randomly allocated to one of four interventions. Each of the interventions will consist of six individual sessions of psychological treatment. The interventions will be manualised to maximise compliance and consistency of treatment.

The interventions are:

- 1. Cognitive-behavioural therapy
- 2. Behavioural therapy
- 3. Motivational interviewing
- 4. Client-centred therapy

Intervention Type

Behavioural

Primary outcome measure

- 1. Gambling symptom severity
- 2. Gambling behaviour:
- 2.1. Frequency
- 2.2. Time spent gambling
- 2.3. Amount spent gambling

Secondary outcome measures

- 1. Gambling related cognitions
- 2. Psychological distress
- 3. Depression
- 4. Anxiety
- 5. Alcohol and substance use
- 6. Gambling related debt and financial problems

Overall study start date

01/01/2013

Completion date

01/12/2015

Eligibility

Key inclusion criteria

- 1. Aged 18 years and over
- 2. Wish to receive treatment for their gambling problem
- 3. Can communicate in the English language

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

276

Key exclusion criteria

- 1. Unable to understand and provide informed consent
- 2. Currently receiving other treatments for their gambling problems or have received such treatment in the past 12 months from a counsellor or therapist
- 3. At risk of self-harm

Date of first enrolment

01/01/2013

Date of final enrolment

01/02/2014

Locations

Countries of recruitment

Australia

Study participating centre Monash University

Notting Hill Australia 3168

Sponsor information

Organisation

Monash University (Australia)

Sponsor details

Problem Gambling Research and Treatment Centre 270 Ferntree Gully Road Notting Hill Australia 3168 +61 (0)419560131 shane.thomas@monash.edu

Sponsor type

University/education

Website

http://www.med.monash.edu.au/pgstudy

ROR

https://ror.org/02bfwt286

Funder(s)

Funder type

Government

Funder Name

The Victorian Department of Justice (Australia)

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?
<u>Protocol article</u>	protocol	24/11/2015		Yes	No