Flinders University

Participant Information Sheet/Consent Form – Person Responsible

Southern Adelaide Local Health Network

Title	SBET: A trial of exposure therapy delivered by phone and internet for sports betting addiction (Sports Betting Exposure Therapy)
Short Title	SBET
Protocol Number	2021/GEM00036
Project Sponsor	Flinders University of South Australia
Coordinating Principal Investigator/ Principal Investigator	Professor Malcolm Battersby
Associate Investigator(s)	Dr David Smith, Ben Riley, Professor Michael Baigent
Location	Southern Adelaide Local Health Network

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, 'SBET: A trial of exposure therapy delivered by phone and internet for sports betting addiction (Sports Betting Exposure Therapy)'. Sports betting has become one of the nation's rapidly increasing forms of gambling addiction, particularly in young males with $1.2 billion lost in 2017 – 18. This research project is based on the recent publication from the SA Statewide Gambling Therapy Service, reporting the successful treatment of 6 young men with sports betting addiction using exposure therapy delivered face to face. You will be invited to be a participant in either the pilot study of 40 participants recruited from all areas of SA or a national study of 140 people recruited using social media from across Australia. The studies will test whether a psychological therapy known as cue exposure therapy (CET) provided for up to 10 sessions delivered using mobile phone or internet video conferencing by a therapist improves gambling behaviour i.e., time spent and financial losses and controls or eliminates the addiction. In the pilot study we will be testing our ability to recruit people who are sports betting and acceptability of the intervention i.e., use of mobile phone and video conferencing to provide therapy.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read

• Consent to take part in the research project
• Consent to the tests and research that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

There has been a rapid increase in legalised forms of gambling in Australia over the last 30 years with electronic gaming machines ('pokies') and more recently internet-based gambling through on-line casinos and sports betting. Sports betting is male dominated and targets adolescents and young men, the next generation of potentially addicted gamblers. Gambling disorder has devastating consequences for the gambler and up to 7 others (Productivity Commission 2010) with not only financial ruin but loss of occupation, family and sometimes leading to a prison sentence.

The treatments we have developed at Statewide Gambling Therapy Service (SGTS) and Flinders University over the last 20 years began with people addicted to pokies using cue exposure (behavioural) therapies (CET). We have refined and adapted this model for all forms of gambling, most recently sports betting. Having a proven effective therapy delivered remotely over 6-10 sessions would be a breakthrough in Australia and world-wide. Careers, families and lives would be saved. The first of the 2 studies, the pilot study, aims to recruit 40 people in SA using social media i.e., Facebook, Instagram, and offer up to 10 sessions of the intervention CET delivered by phone or video conferencing to all 40 people to test the recruitment and delivery of the intervention by phone and internet with a therapist. This will inform a larger national study where we will aim to recruit 140 people and randomise them (a process used to reduce bias whereby a computer program gives a person a 50:50 chance of being allocated to one of two groups) to either the intervention CET or an alternative therapy (usual care). This comparison therapy of up to 10 sessions is delivered by phone or video conferencing with a therapist, consisting of education, self-monitoring and setting goals for alternative activities to gambling. This will test whether CET works for people from all types of backgrounds, education, occupation and location across Australia.

This research has been initiated by the study doctor, Professor Malcolm Battersby.

This research has been funded by Flinders University and the SA Department of Human Services.

3 What does participation in this research involve?

You are being invited to participate in a research project for either a pilot study (Phase 1) of 40 people or a research project (phase 2) of 140 people. The intervention (therapy) will be delivered by trained mental health professionals based at Flinders Medical Centre, Adelaide.

Once you give consent to be involved in one of the 2 studies you will also be asked to complete some questionnaires on your gambling and mental health. The questionnaires will take between 10- 20 minutes to complete. You will be asked to complete them at the beginning of the project (baseline), at 4 weeks, 3 months and 5 months after baseline in the pilot study and 4 weeks, 3 months and 12 months after baseline in the phase 2 randomised study. Once the questionnaires are completed the research assistant (RA) will arrange for the trial therapist to contact you within 48 hours arrange commencement of CET (phase 1).

For phase 2, the RA will contact the Flinders Clinical Trials centre to obtain the randomisation allocation for you to one of the 2 groups. They will then arrange for the appropriate therapist to contact you to commence the first therapy session. The 2 types of therapy are:
Cue Exposure Therapy (CET): The first session includes asking you to put Money Management in place e.g., ceasing or pausing credit card/phone/eftpos access. You will receive a standard mental health and gambling assessment. The CET treatment is delivered in up to 10 individual sessions of 30-60minutes and conducted according to a detailed manual. You may receive fewer or a greater number of sessions depending on the pace at which you move through the range of triggers or cues to your gambling urge. This is a collaborative process between therapist and participant and utilised cues such as their smartphone, images of sports betting websites and preferred sports. Exposure is graded up to watching a live sporting match online until the urge to gamble is eliminated.

Control therapy (Usual care): Up to 10 sessions of 30-60 minutes duration guided by a client workbook consisting of education about gambling risks and harms, how the technology works and the psychology of gambling. Participants will be asked to monitor their gambling cognitions, gambling time and money spent/lost through use of a monitoring diary and assisted to set life recreational goals as alternatives to gambling.

All participants will be asked to complete questionnaires, provided on-line via email at the beginning of each treatment session and additional questionnaires as above at commencement, session 4, end of treatment session 10 and 2 month post treatment follow up (phase 1) and 3 month and 12 month post treatment (phase 2).

For the phase 1 pilot, 6 participants will be asked to participate in a semi-structured interview over the phone lasting 15-30 minutes asking them about of the acceptability and feasibility of the recruitment process and intervention itself and any suggestions for improvement.

In addition, you will be asked to list any medications you are currently prescribed, and information about your medical and psychiatric history. There are no follow up requirements of you in this research project.

Participants will need to agree to being in the study and sign a consent form prior to any study assessments being performed.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way that allows study doctors or participants to make informed conclusions.

There are no costs associated with participating in this research project, nor will you be paid. To compensate for your time, you will be offered a supermarket gift voucher of $30 after completion of baseline questionnaires and at the end of follow up questionnaires (2 moths for the pilot and 12 months for the phase 2 study), total $60.

If you have a local doctor, we strongly recommend that you inform them of your participation in this research project or if you so wish, we are happy to send your GP a letter informing them of your involvement in this research.

4 What do I have to do?

In addition to completing trial questionnaires, you will be asked to read information about the therapy and workbooks which step you through the therapy process. The therapy for CET consists of you identifying your triggers to gambling urges and exposing yourself to these urges until they reduce (20-40 minutes) at least by half. You will be asked to practice these tasks daily. You will also be asked to record your tasks on a homework sheet and discuss them with your therapist. For the alternative or control therapy the process is similar, using a workbook to work stepwise through a series of tasks to be completed in your own time at home and recorded to discuss with your therapist. Collaboratively with the therapist you will decide on the following

week's tasks in a flexible manner which is adapted to your personal circumstances and preferences.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect any routine treatment that you are receiving.

6 What are the alternatives to participation?

If you decide that you want help for your gambling outside of this research project, there is a national gambling help phone number 1800 858 858, and in each state and territory there are free government funded gambling help services or through your GP you can access private gambling help services or Medicare funded access to psychologists and mental health professionals.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. You may of course benefit from a reduction in your time spent gambling and money lost. You may choose to be completely abstinent from sports betting or chose to gamble in a controlled way. If the studies show improved outcomes i.e., reduced gambling, provided by a remotely delivered intervention, people with sports betting addiction across Australia and internationally could benefit by easy access to an effective proven treatment without the necessity of needing to have face to face therapy in a clinic.

8 What are the possible risks and disadvantages of taking part?

There are minimal potential risks associated with the studies, pilot or randomised trial themselves as the intervention is psychological and aimed at reducing the problem. As each therapy session is conducted live with a therapist, the risk or burden is monitored carefully and tasks and progress modified based on the level of comfort and motivation of the participant, i.e., although the therapy is based on a treatment manual, use of the manual is applied flexibly. People with gambling disorder have inherent risks of suicidality after significant financial losses so involvement in these studies will reduce this risk by the person having access to trained therapists who routinely assess suicide risk at each session. The burden on the participant is in having to complete questionnaires ie 10-15 minutes at each therapy session and 30-40 minutes at each trial data collection point. These are routinely provided as part of usual care of the Statewide Gambling Therapy Service and in our experience impose minimal burden to participants.

9 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the condition that is being studied. If this happens, your study doctor will tell you about it and

discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

10 Can I have other treatments during this research project?

Whilst you are participating in this research project it is important to tell the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. During the study you will be able to continue to take any medications already prescribed to you for gambling or any other medical or psychiatric condition.

11 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

12 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly if the therapy staff were unable to continue to provide the therapy. However, although there may be some delay an alternative therapist will be made available to assist you to complete the therapy.

13 What happens when the research project ends?

We aim to complete the pilot project in 12 months, and the main project in 26 months. Depending on which project you partake, you will receive a summary of the results at the end of those periods.

The results of the pilot study will be provided to you to let you know that the data collection and study have been completed and that your contribution has been important for preparation for the larger study. You will be informed by email and failing that by phone call from one of the trial investigators. For the main study, you will be informed in 2 steps, 1 to let you know that trial is completed i.e., all participants have been recruited and received their therapy and the data collected and 2 when the results are known and published i.e., the comparison between groups to show if any differences between the 2 interventions were detected and to give you an indication of where the research could lead. If at the end of the trial you wish to know which arm of the trial you received you can request this from the study investigators (below) and you will be informed. Both stages of feedback will be provided by a standardised email to you or failing that by phone from the RA or one of the trial investigators.

Part 2 How is the research project being conducted?

14 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Confidentiality of data will be ensured by using de-identified encrypted data, pass-coded computers. The only site where the study number and a patient's name will be co-located is the clinical record. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. If specific participants are to be mentioned in the publication, they would simply be referred to as 'Participant #', where '#' denotes the chronological number of the participants. Specific information about the participant will be stored in the trial clinical record, which will not be entered into the publication.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project *and for the future research described in Section 16* that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

15 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

If you suffer any distress or psychological injury as a result of this research project, you should contact the study team as soon as possible. They will assist you in arranging appropriate treatment and support.

16 Who is organising and funding the research?

This research project is being conducted by Professor Malcolm Battersby. The pilot project is being funded by Flinders University and the SA Department of Human Services with a grant of $50,000. The main study will be the subject of an application to the NHMRC Partnership grant round in 2023.

Flinders University and SA Health may benefit financially from this research project if, for example, the project assists the 2 organisations to provide training programs for therapists in the treatment model.

By taking part in this research project you agree that data generated from the analysis of your involvement may be provided to Flinders University and SA Health. Flinders University and SA Health may directly or indirectly benefit financially from knowledge acquired through the analysis of your data.

You will not benefit financially from your involvement in this research project even if, the knowledge acquired from analysis of your data prove to be of commercial value to Flinders University and SA Health.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Flinders University and SA Health, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

17 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the *Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC)*.
This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

18 Further information and who to contact

To participate in this study please contact Prof Malcolm Battersby at Malcolm.battersby@flinders.edu.au or 84042314. Based on your preference Prof Battersby will contact you by telephone or email to answer any questions and provide you with a consent form. Consent can be given on a signed printed form or via an email. If you consent to be part of the study, we will give you a personal code and organise your participation.

Clinical contact person

Name	Professor Malcolm Battersby
Position	Head of Psychiatry, Flinders College of Medicine and Public Health
Telephone	84042314
Email	Malcolm.battersby@flinders.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Position	Manager, Research Governance and Ethics
Telephone	8204 4507
Email	Health.SALHNOfficeforResearch@sa.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC)
Telephone	61 8 82046285
Email	Health.SALHNOfficeforResearch@sa.gov.au

Consent Form - *Adult providing own consent*

Title	SBET: A trial of exposure therapy delivered by phone and internet for sports betting addiction (Sports Betting Exposure Therapy)
Short Title	SBET
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Associate Investigator(s))	Dr David Smith, Ben Riley, Professor Michael Baigent
Location	Southern Adelaide Local Health Network

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Flinders University concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

Title	SBET: A trial of exposure therapy delivered by phone and internet for sports betting addiction (Sports Betting Exposure Therapy)
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Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Southern Adelaide Local Health.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.