Protocol

An ethics application has two forms and is submitted via GEMS.

1. The HREA form ensures your project complies with the ethical considerations for research, outlined in the National Statement on the Ethical Conduct in Human Research.
2. The protocol provides the SAC HREC with the design, objectives, methodology and rationale on how the research project will be conducted.
   - HREA submission guidelines are available on our website.
   - Training resources, including a free Good Clinical Practice course can be found on our website

How to use this document:

Please treat this as a piece of academic writing, taking into careful consideration readability, spelling and grammar.

The preparation of a research protocol is an important first step in the research process. The development of a written protocol ensures that research activities are well-planned from the outset, and that a clear record is available for investigators to refer to throughout the project.

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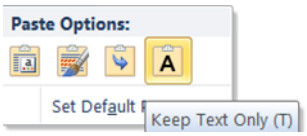

Please ensure you add a version number and date in the footer of this document

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

Project team

The person listed as the Chief Investigator / Principal Investigator is responsible for the conduct of the research and listed study staff until completion of the project.

A student cannot be listed as the Coordinating Principal Investigator or Principal Investigator

Explain the role in the study that each Investigator will perform at each site and clearly state whether Investigators will work on or off the relevant public LHN site(s).

Name: Professor Malcolm Battersby
Institutional affiliation: SALHN Mental Health and College of Medicine and Public Health Flinders University
What is the position of this person on the research project? Chief Investigator
What are the research activities this person will be responsible for: Overall conduct of the trial Does this person have a current Good Clinical Practice certificate? ☒ Yes / ☐ No

The SAC HREC encourage all researchers to complete their GCP training. A free Good Clinical Practice course can be found on our website.	
Department and department address: Discipline of Psychiatry, Margaret Tobin Centre, Flinders Medical Centre, Bedford Park, 5042	
Contact details: a Health or University email address is preferred	Phone: 08 84042314 Email: Malcolm.battersby@sa.gov.au
Name: Dr David Smith	
Institutional affiliation: College of Medicine and Public Health Flinders University	
What is the position of this person on the research project? Investigator	
What are the research activities this person will be responsible for: Trial design, statistical, data collating, analysis and reporting. Does this person have a current Good Clinical Practice certificate? ☐ Yes / ☒ No The SAC HREC encourage all researchers to complete their GCP training. A free Good Clinical Practice course can be found on our website	
Department and department address: Discipline of Psychiatry, Margaret Tobin Centre, Flinders Medical Centre, Bedford Park, 5042	
Contact details: a Health or University email address must be used ☐ I am the contact person for this project	Phone: 08 84042314 Email: david.smith@flinders.edu.au

Name: Ben Riley
Institutional affiliation: SALHN Mental Health and College of Medicine and Public Health, Flinders University
What is the position of this person on the research project? Investigator
What are the research activities this person will be responsible for: Ben will be responsible for recruitment, therapy and supervision of other therapists in the pilot study, data analysis, interpretation and report writing. Does this person have a current Good Clinical Practice certificate? ☒ Yes / ☐ No The SAC HREC encourage all researchers to complete their GCP training. A free Good Clinical Practice course can be found on our website
Department and department address: Flinders Psychological Therapy Services, SALHN Mental Health Division, The Flats, Flinders Drive, Flinders Medical Centre, SA 5042

Contact details: a Health or University email address must be used ☐ I am the contact person for this project	Phone: 08 82046982 Email: ben.riley@sa.gov.au

Name: Professor Michael Baigent
Institutional affiliation: SALHN Mental Health and College of Medicine and Public Health Flinders University
What is the position of this person on the research project? Investigator
What are the research activities this person will be responsible for: Overall management and supervision of the clinical aspects of the trial ie patient outcomes and allocation of suitably qualified therapists to deliver the intervention. He will oversee data collection and contribute to data analysis, interpretation and report writing. Does this person have a current Good Clinical Practice certificate? ☒ Yes / ☐ No The SAC HREC encourage all researchers to complete their GCP training. A free Good Clinical Practice course can be found on our website
Department and department address: Flinders Psychological Therapy Services, SALHN Mental Health Division, The Flats, Flinders Drive, Flinders Medical Centre, SA 5042

Contact details: a Health or University email address must be used ☐ I am the contact person for this project	Phone: 08 82046982 Email: Michael.baigent@sa.gov.au

Resources

What resources are necessary for the project to be conducted? Phase 1 pilot: Funding to support a sports betting therapist(s) for 6 months, a project officer, social media recruitment and statistical support Phase 2 randomised controlled trial (RCT) Funding to support 2 sports betting therapists for 9 months, a trial manager, project officer, social media recruitment, gift vouchers and statistical support
Please declare what funding support and amount is being sought or has been secured for this project: Funding of $50,000 has been awarded by the Flinders University Innovation Partnership Seed Grants (IPSG), $25,000 of which has been provided by the SA Department of Human Services, Office for Problem Gambling. Phase 2 funding is being sought from other states ie., Victorian Problem Gambling Foundation. In 2022 funding will also be sought from a NHMRC partnership application, with SALHN, SA Department of Human Services in round 3 totalling $450,000 to conduct the RCT nationally.

Project design

Please refer to the National Statement Chapter 3.1 Elements of Research for guidance on to how to ensure this research is conducted in line with core ethical principles.

Introduction – Please provide a brief overview of the study:

Sports betting has become one of the nation's rapidly increasing forms of gambling addiction with $1.235 billion lost in 2017 - 18, particularly in young males. This proposal is based on the recent publication from the SA Statewide Gambling Therapy Service, Riley et al (2021) reporting the successful treatment of 6 young men with sports betting addiction using exposure therapy delivered face to face. This pilot study aims to recruit 40 participants from all areas of SA using social media and provide exposure therapy (ET) for up to 10 sessions using mobile phone or internet. Outcomes will be pre - post outcomes in gambling behaviour, anxiety and depression; feasibility and acceptability: ability to recruit people who are sports betting and acceptability of the intervention i.e., number of sessions attended and use of mobile phone and video conferencing to provide therapy.

Background and literature review – please provide an overview of why the study needs to be done and explain to the committee how the literature review demonstrates the originality and relevance of your 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. Australians have become the world's biggest gamblers per head of population with total losses in 2018-2019 of $24.895 billion, $1.235 of which was sports betting an increase of 16% from the previous year. Between 1.5- 4% of the Australian population have a gambling problem and15% of regular pokies players who have gambling disorder or problem gambling contribute 40% of gambling revenue from pokies. Sports betting is male dominated and targets adolescents and young men, the next generation of 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 incarceration. In two of our prison studies 55-70% of inmates had a lifelong gambling disorder. The interventions 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) and the addition of cognitive therapy. 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. Flinders and SGTS could become the centre of this form of therapy for sports betting and any other form of on-line gambling internationally. Careers, families and lives would be saved.

This phase 1 pilot proposal aims to recruit 40 participants from all areas of SA and provide CET using mobile phone or internet in contrast to those who have received the intervention from SGTS face in a clinic setting as described in the published 6 case studies. This would provide the data to inform a phase 2 national randomised controlled trial with funding sought from other states and/or NHMRC Partnership grant.

Phase 2 RCT: Partners will be sought from SALHN, SA DHS, Victorian and NSW Problem Gambling Foundation (Vict) and Gambling Aware (NSW) and other state and territory gambling

help service funding bodies towards a national randomised controlled trial (RCT) aiming to randomise 140 sports betting individuals across Australia. Participants will be randomised to either CET or usual care – a therapist delivered on-line/phone educational and motivational workbook to provide equivalent attention.

Significance

This study provides a state-of-the-art digital intervention for the treatment of sport betting and other internet-based addictions. It addresses the Office of Problem Gambling, SA government's responsibility and commitment to reduce the effects of problem gambling in SA and potentially apply this to the rest of Australia and internationally. As problem gambling disproportionately affects lower socio-economic groups including our indigenous population this intervention addresses the University's values and strategy in prioritising socially disadvantaged populations

Hypothesis - What is the scientifically valid research question being asked?

Phase 1 pilot: As a pilot study we are not hypothesis testing, instead we are interested in acceptability and feasibility of providing the intervention by phone or videoconferencing instead of face to face. Feasibility is critical in terms of 1) recruitment ie whether we can recruit using on-line ie social media links to sports betting apps, Facebook, Instagram etc to recruit people who are having gambling problems either help-seeking (direct contact to SGTS) or not help-seeking 2) delivery of the intervention CET remotely ie uptake and completion of the therapy program

Phase 2 RCT: CET provided by phone and/or video conferencing will be more efficacious at reducing problem gambling and gambling behaviours including money lost than usual care of education and attention.

Aims - What do the investigators intend to achieve with this research project

Phase 1:

1. To evaluate whether we can use social media advertising to recruit 40 sports betting problem gamblers over 3 months who are either help seeking or not actively help seeking.

2 To deliver the CET intervention in up to 10 sessions by phone or video conferencing and determine the acceptability of this approach and the proportion who complete the intervention

Phase 2:

Evaluate whether CET delivered by phone or videoconferencing significantly reduces gambling behaviour compared to usual care of attention and education

Objectives - How will investigators achieve the aims of the research project?

Phase 1:

We will use paid advertising and informal i.e., study initiated social media and contacts with sporting clubs through the SA Office of Problem Gambling to advertise this research study. We have experience of delivering phone and on-line psychological interventions by phone and videoconferencing (HealthDirect) during the COVID pandemic for people presenting the FMC ED in crisis and providing IAPT or MyAPT successfully. We will build on this experience and the use of workbooks to guide a gambler through the treatment program.

Phase 2: to use the learnings from the phase 1 pilot to refine the recruitment of people who have problematic sports betting and deliver a randomised controlled trial nationally to determine if CET is efficacious at reducing gambling behaviour

Expected outcomes - What do the investigators anticipate the outcomes of this research will be?

Outcomes will be pre - post quantified validated measures of gambling behaviour, anxiety and depression; feasibility and acceptability: ability to recruit people who are sports betting and acceptability of the intervention i.e., number of sessions attended and use of mobile phone and video conferencing to provide therapy. Pre and post outcome data will support existing evidence from our own and others trials to confirm the effect sizes and sample size for a larger phase 2 randomised controlled trial

Phase 2:

Use the learnings and effect size change in the CET group from phase 1 to implement a randomised controlled trial and recruit 140 people who provide consent and baseline data and test the efficacy of the experimental intervention (CET) versus control intervention.

Rationale / justification - How the research will fill any gaps and/or contribute to the field of research or contribute to existing or improved practice?

There are no proven treatments for sports betting internationally. This studies phase 1 and 2 would be the first beyond a case series that would demonstrate pre-post outcome measures to test a highly accessible psychological treatment for sports betting gambling disorder.

Research project setting - i.e. Where is the research being conducted i.e. FMC, GP Plus Marion, Noarlunga Hospital, Tonsley building, Sturt Campus, online forums and alternatives

Please ensure you list the site plus clinic/department / service.

The study will be based at The Flats – Flinders Psychological Therapy Services FMC site from where the therapists will deliver CET and usual care by phone or internet remotely to either SA or whole of Australia. Recruitment will occur for individuals across the whole of SA for phase 1 and all Australia for phase 2.

Methodological approach - clearly describe the specific procedures or techniques that will be used to answer the research question and meet the aims.

The intervention: in the published 6 cases treated by SGTS CET was provided face to face by experienced SGTS staff using a standardised workbook adapted for sports betting. The graded exposure-based approach identifies triggers which elicit a gambling urge and the person then systematically using homework tasks, grades their approach to each trigger until habituation of the gambling urge occurs. Ultimately all urges to gamble are extinguished and the person gains control over their gambling either through abstinence or occasional gambling.

Pilot trial phase 1 (SA)

Recruitment: 40 subjects to be recruited over a 3-month period in SA using social media, i.e., Facebook and Instagram to recruit on-line sports betting gamblers and through the OPG Gambling Help Services throughout SA.

Design: this would be a 12-month single arm trial with all participants being offered CET. Participants would receive up to 10 sessions (30-60 mins) provided over 2 months and follow up for another 3 months. We will recruit until we have 40 people who have provided signed consent forms and baseline questionnaires. All will be offered the intervention. As for all psychological interventions, of the 40, a proportion will not attend a single session (~5%), some will attend a single assessment only session (~10%) and others only 1 assessment and 1-2 therapy sessions (~20%) leaving about 65% who attend 4 or more sessions. (ie one assessment + 3 therapy sessions). This provides a naturalistic comparison group ie 35% of the sample who received no or minimal intervention compared to the intervention group (65%) who we will define as having ‘an adequate dose’ of the intervention. We will also conduct a per

protocol analysis of those who completed all 10 sessions to see the effect of the full dose of the intervention.

Phase 2:

140 subjects will be randomised to intervention (CET) or control ie usual care, in a 2-arm parallel 26 month randomised controlled trial, each arm receiving up to 10 sessions over 12 weeks delivered by phone and/or videoconferencing. Each participant will be followed for 12 months post intervention to determine outcomes of gambling behaviour, problem gambling severity, anxiety, depression and work and social adjustment.

Consumer and Community engagement – investigators are encouraged to consult with Consumer and Community groups with the design of their research. Please outline any consultation that has occurred.

SGTS has an active consumer group led by Mr Allan Green a former client of SGTS who has recovered from a gambling addiction. He is employed 0.1FTE by SALHN to provide support to gamblers about to start treatment and during treatment. He has provided input to the design of the workbook and will be asked to continue his current role in contacting participants in the trial during their therapy to provide education and support as well as obtain feedback on the acceptability of the intervention.

What are your outcome measures?

Primary outcome. Phase 1: Outcome assessments will occur at baseline, post-treatment (12 weeks) and follow-up at 2-month post-treatment.

Phase 2: Outcome assessments will occur at baseline, post-treatment (12 weeks) and follow-up at 3 and 12-month post-treatment.

Primary outcome: The participant-rated primary outcome measure is the Victorian Gambling Screen (VGS) harm to self-subscale (Likert scoring 0, 1, 2, 3, 4; range 0-60); a score of 21and aabove identifies a person as a problem gambler) relating to the person's experiences in the person's experiences in the previous 4 weeks.

Secondary outcomes: number of days spent gambling and amount of money spent per day gambling will be measured over the previous 1 month, PHQ-9 (depression) GAD-7 (anxiety). WSAS (work and handicap). Other gambling measures include the Gambling Urge Scale (GUS) where higher scores indicate greater urges to gamble with a range 0–42 and the Gambling Related Cognitions Scale (GRCS) which is a 23-item seven-point Likert scale that records the degree of agreement with common thoughts associated with gambling disorder.

Phase 1 Qualitative: Semi-structured interviews with purposefully chosen (age above and below 20, those who improved/recovered/those who dropped out/did not recover) 6 intervention participants and 2 therapists to determine recruitment barriers and enablers, acceptability and feasibility and any improvements to the intervention or delivery and recruitment. Of particular interest will be the on-line and social media strategies used to recruit non help seeking sports betters.

Project duration:

Phase 1 timeline: 2 months set up, 3 months recruitment, 6 months intervention (3 months during recruitment and another 3 months from end of recruitment), 2 months follow up, 2 months data analysis and write up. – total 12 months.

Phase 2 timeline: 2 months set up, 6 months recruitment, 9 months intervention (6 months during recruitment and another 3 months from end of recruitment) 12 months follow up, 3 months data analysis and write up – total 26 months.

Participant selection and activities

Explain how participants will be recruited or how their data will be selected (e.g. for a registry).

Describe sources and methods that will be employed in the identification and recruitment/selection of potential participants (e.g., clinics, referring doctors, adverts, and time periods) or of historical data (e.g. medical records, databases).

You should make a distinction between how you will recruit/select control participants compared to other groups if performing a comparative intervention.

How many participants will be selected for the study?

Phase 1 40

Phase 2 - 140

How are they identified as possible participants?

Help seekers who are sports betters who contact SGTS either through existing channels eg SGTS website or GP referral will be screened for eligibility and those non help seekers will be approached through advertising the study on social media ie Facebook, Instagram, and asked to provide contact details to the trial website (see below). A research assistant (RA) will then contact the participant to check eligibility and provide trial information.

Pre-screen for eligibility – waiver of consent

The recruitment method must be compliant with the Health Care Act 2008. If you need to access a patient's medical records to pre-screen for eligible participants, and you do not have prior patient consent to do so or are not part of the patient's clinical care team, you will need to apply for an exemption under 93(3)(f).

Are you requesting a waiver of consent to pre-screen?

☒ No – I am part of the patient's clinical care team.

☐ Yes

Under s93(3),(f) of the Health Care Act 2008, we wish to apply for an exemption of patient consent to access their personal information for research purposes. In order to identify suitable participants for this research project, <specify who or a title i.e. study coordinator> will be required to access <specify what is being accessed>, prior to obtaining consent from the patient.

How will participants be recruited into the study? Please provide a detailed step by step description of the recruitment methods i.e. flyers, adverts, direct approach, invitation letter etc.

Currently SGTS receives referrals from GPs, Gambling Help services and self-referral usually by word of mouth or the SGTS website. For this study, we will recruit from this source (help seekers) and for non-help seekers set up advertisements from Flinders University Facebook

and the University's links with Adelaide United football A League club (men and women) and Breakthrough Foundation links with the Adelaide Crows AFL club (men and women). The study advertising will be timed with a media story and the playing of A league and AFL games in Adelaide. In phase 1 this should be adequate exposure to recruit 40 people in the 3 month period.

For phase 2 ie nationally, our links with the NSW Gambling Aware and Victorian Problem Gambling Foundation advertising and awareness campaigns will provide broad social media distribution and if those strategies are inadequate, we will use paid advertisements on Facebook, Instagram and Google adds linked to gambling , sports betting, sites or with words like 'gambling', 'sports betting', 'odds', 'bet', 'betting', 'stakes' etc as per https://www.si.com/betting/2020/05/13/sports-betting-terms-definitions-gambling.

How will they be approached? Which staff / research team members are approaching the participants? When is this occurring? I.e. clinic, inpatient.

The advertisement will read ' Are you worried about the amount of time or money you spend sports betting and want to help doctors to find out the best ways to help someone fix their gambling problem? ' If they click on this link they will be transferred to questions a) age 18 or older? b) resident in SA - postcode? For phase 2 the second question will be resident in Australia (postcode) ?

If yes to both, they will be transferred to the trial website on Redcap and asked to provide either or both their mobile phone or email address. The trial research officer will then use this information to contact them within 48 hours to explain the study and ensure they are eligible.

What are the inclusion and exclusion criteria? - Detail the characteristics that clearly describe the study population that are required to be either included or excluded in the research.

Inclusion: includes sports betting on any of the commercially advertised sports betting gambling sites at least once per month e.g., Sports bet and losing amounts that the person believes is excessive or time spent is excessive, willingness to have counselling sessions recorded and to provide follow-up data, age greater than 17, access to a smart phone and or internet. Receiving or having received psychological treatment for a gambling problem in the last 12 months is not an exclusion.

Exclusion: mental distress e.g., psychosis or suicidality so as not to be able to give informed consent. Concurrent other forms of gambling e.g., pokies, TAB or lotto are acceptable as are co-morbidities of depression, anxiety and other addictions e.g., alcohol or tobacco.

Participant commitment -What will their participation involve? I.e. study visits, procedures, tests, tissue samples, questionnaires, wearing of any devices.

The RA will contact the person to arrange a suitable time to go through the trial information, providing the patient information and consent form (PICF) electronically. If the person gives consent, they may sign this form electronically and return it electronically or print and scan or

print and post the form. They will also be asked to complete the baseline questionnaires at this or a subsequent session These are returned as above. Once the questionnaires are completed the RA will arrange for the trial therapist to contact the person to commence CET (phase 1).

For phase 2, at this point the RA will contact the Clinical Trials centre to obtain the randomisation allocation. They will then provide the appropriate therapist information to contact the person to commence the first therapy session.

Intervention: CET. The first session includes asking the person to put Money Management in place ie ceasing or pausing credit card/phone/efpost access, cancelling phone and internet gambling accounts, arranging for a daily or weekly allowance managed by a significant other. All participants are given a standardised treatment rationale during their first session and checked if they agree to proceed with the treatment plan. They are also helped to define a problem statement and end of treatment goal. They receive a standard mental health and CBT assessment screening for co-morbid psychiatric disorders and risk to self or others.

The CET treatment is delivered in individual sessions and conducted according to a detailed manual which is adapted from one used previously in a randomised control trial (Smith et al. 2015). Treatment comprises up to 10 weekly 30-60-min sessions, though participants may have receive fewer or a greater number of sessions depending on the pace at which they moved through their graded cue exposure hierarchy.

During the second session an initial hierarchy of gambling cues is developed which is altered according to the clients' insights and responses throughout treatment. This is a collaborative process between therapist and participant and utilised cues such as their smartphone, images of sports betting websites and preferred sports, and videos of sporting matches. Exposure is graded up to watching a live sporting match online or on the television while holding a smartphone with betting account credits and habituating to the urge to gamble. For mixed gamblers, habituation tasks also include in vivo (live) exposure in a gambling venue holding money and habituating to the urge to gamble. Clients are encouraged to perform CET homework regularly between session. Once participants extinguish their urge response from a cue, they moved to the next task on their graded hierarchy.

Control (phase 2): Usual care: Up to 10 sessions described in a workbook will be provided of 30-60 minutes duration consisting of education about gambling risks and harms, the technology and psychology of gambling, skill vs computer algorithms which favour the gambling company, the psychology of intermittent reinforcement. 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 as per usual care for gambling clients taking 10-15 minutes ie Gambling time and money spent, PHQ-9 depression (q 9 to check for suicidal behaviour), GAD7 anxiety and additional questionnaires as above at baseline (30-40 minutes), 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 phase 1, 6 participants and 6 significant others will be asked to participate in a semi-structured interview of 15-30 minutes of the acceptability and feasibility of the recruitment process and intervention.

Participant follow up – how are participants monitored during the study?

Participants are followed up weekly at each therapy session and at 2 months follow up (phase 1) by the therapist both from use of questionnaire data and phone or video observation and clinical contact and for phase 2, at 3 and 12 months post treatment by the RA.

All participants are monitored through the clinical on-line data collection system PC-MIS and weekly therapist supervision sessions provided by CIs, Battersby, Riley and Baigent

Consent

Please refer to the National Statement 2.2 for guidance on consenting participants.

Where possible, informed consent should be sought from individuals to participate in research or to access their data for research purposes.

Consent can be provided in writing, implied (i.e. by return of a survey), opt in, opt out or verbally.

If consent cannot be obtained from the participant, a waiver of consent can be applied for which is reviewed and approved by the SAC HREC. The waiver of consent must be justified using the National Statement chapter 2.3.9 and 2.3.10 (a) to (i) in the HREA.

The investigator(s) should: ·Determine, according to level of risk to participants, who of the study team is appropriate to lead the participant informed consent process. This should be documented on the "Delegation of Duties" log. (ICH GCP 5.7)

How you will be obtaining consent and/or what alternatives you will be using: All eligible participants will be emailed the patient information and consent forms when they have responded to the trial advertisement and contacted by the RA. The RA will provide a verbal explanation of the trial and allow enough time (20-40 minutes) for the participant to read the PICF and ask questions or to discuss the trial with their family or significant others and if necessary, respond to the RA at a subsequent appointment. If the person provides consent the form can be signed, scanned and emailed to the RA/trial email address or posted or the signature provided electronically using docusign or pdf with signature provisions.
Are you requesting a waiver of consent ☐ **Yes –** please justify why the waiver of consent is appropriate in the HREA ☒ **No**
Which investigators will issue the information sheets and consent forms: None of the investigators will issue PICFs only the RA
How much time will participants have to consider participation: 20-40 minutes to read the trial information or as long as they wish including additional time to discuss with family and friends
Please specify which investigators will obtain consent from participants: None of the investigators will obtain consent only the RA
Will there be an opportunity to confirm or renegotiate consent during the research project? – I.e. the capacity of the participant changes or the terms of consent / participation changes. Yes, the capacity and interest in the project by the participant may change between being given the information sheet and deciding to consent partly dependent on their losses and level of concern about their gambling problem. The participant will be given ample time to consider interest in the project ie up to 7 days and may approach or be approached by mutual consent

fby the RA. They may able to provide consent and commence the study at any time during the recruitment period (3 months phase, 6 months phase 2).

Who will be confirming or renegotiating consent with participants and what process will be undertaken?

The RA will confirm or renegotiate consent

Conflicts of interest: Please refer to the National Statement chapter 5.4, and your institutional policy for guidance.

☐ Yes / ☒ No

Please provide details of the conflict of interest:

How will the conflict be managed?

Ethical considerations

Please describe the risk and burden associated with your research. The National Statement chapter 2.1 provides guidance and advice on the definition of risk and how to gauge and manage it.

There are minimal potential risks associated with the studies, pilot or RCT themselves as the intervention is psychological and aimed at reducing the problem. As each therapy session is conduced 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 access to 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.

How will any risks be managed?

Suicide risk is managed by a screening question (q9 of the PHQ-9) at the start of each session, if active suicidal thoughts or plans are detected the therapist will abandon the therapy content and specifically focus on further assessment of suicidality and plans for the person to access help through the local mental health service, GP, Emergency Department or state mental health triage phone number. Furthermore, a partner or significant other is advised with the participant's approval to be involved in the supporting the participant in the study and they will be asked to monitor distress and suicidality and provided with options for help seeking as appropriate. As the PHQ-9, including qu 9 which asks about suicidal ideation is administered by the therapist at each session (both intervention and controls) any suicidality will be addressed by the therapist. As

part of usual care, therapists use mobile phone contact via text messaging as 2-way communication between sessions so the participant may contact the therapist if they are distressed. This will not be initiated by the therapist unless they are concerned about the participant based on the session they have just had or text or voice messages received from the participant which indicate distress or suicidality.

Benefits – please identify and explain the expected outcomes and benefits of the study

There will be benefits to the individual involved in the study as per the published case studies by having their gambling urges either eliminated or under control and improved finances and quality of life. If the studies show improved outcomes by a remotely delivered intervention people with sports betting addiction across Australia and internationally could benefit by improved access to an effective treatment.

Individuals consenting to the study will receive a supermarket gift voucher of $30 once baseline questionnaires are completed and at the final follow up data collection point (ie $60 per person) to compensate for their time to be involved with the study.

Does a dependant or unequal relationship exist between the participant and the researcher?

Please refer to the National Statement 4.3 for advice and guidance on how to manage this**.**

☐ Yes -

How will the dependant / unequal relationship be managed? Click here to enter text.

☒ No

Data management – as required in addition to that outlined in your HREA

As per the National Statement 3.1.45, researchers must have a data management plan in place.

The Office for Research would like to remind researchers that the disposal of research records must be made in accordance with The State Records Act 1997 (the Act). Under that Act records must be disposed of as outlined in the general disposal schedules.

Public health institutions fall under general disposal schedule 28. As per item 6 of general disposal schedule 28, the researchers records of research including results, notes, completed questionnaires, signed consent forms, data, reports, and study findings must be kept for 15 years after the research project has been completed before being destroyed. This includes all types of research.

Universities fall under general disposal schedule 24. As per section 9 of general disposal schedule 24 research data records should be kept for a duration according to the nature of the study. For short term research projects such as study research projects, data should be kept for 1 year after last action. Research data from clinical trials should be kept for 15 years after action completed. All other research data and results should be kept for 5 years after publication, conclusion, or abandonment of the project. Data should be destroyed after the mandatory retention period.

Unless informed consent has been obtained from the participant, or legally authorised person, or the HREC has expressly approved otherwise, personal information used or disclosed for research purposes, must be de-identified. Only SA Health employees will perform the de-identification process prior to releasing the information for research purposes.

Who will collect the study data / information? Only SA Health employees can access patient data for research purposes. Students and non-SA Health employees cannot access patient records for research purposes under any circumstances.

Three of the 4 investigators are SA Health employees (Battersby, Riley and Baigent) and will collect SA Health data

What format will the data or information be stored?

Upon collection the data will be securely transferred to the secured University virtual private network for processing. The data will be stored in a secure research data storage repository at Flinders University, managed by the Flinders University, Information and Digital Services (IDS) department

Please provide details regarding training of the research team on maintaining the integrity and security of the data -

CI Battersby will oversee trial data management and integrity, however CI David Smith biostatistician has considerable expertise in information management, and data protection.CI Smith will manage secure data transfer and data retention, data handling (integrity) and data storage procedures so that the entire team is familiar with the privacy, integrity and security requirements and measures in place.

What conditions can the data be accessed or granted to others?

Data access will not be granted to others outside the project team.

How will the research data be stored and what security measures are in place to protect it?

The data will be stored in the secure research data storage repository at Flinders University, managed by the Flinders University, Information and Digital Services (IDS) department. The security measures are defined by the University Information Security Policy for data storage and retention, which meets the NHMRC guidelines. The research data will have a Research Data Management Plan as per the Flinders requirement under the Management of Research Data and Primary Materials Policy. In addition, due to the sensitivity of the data, it will be de-identified and encrypted.

How will you provide access to, disclose, use/re-use or transfer the data?

The data is accessible only to the project team using restricted access to the security data storage repository. Outside of study investigators de-identified data will only be provided to external researchers who will have to apply for access to data after the main findings are published. These requests will be assessed by the study investigators.

How long will the data be retained for?

☒ The data will be kept for 15 years – for all SA Health research

☐ The data will be kept for 5 years – for all University research,

What plans are in place to store / archive the study data once the research is completed?

Upon completion of the project an HREC report will be submitted. The data will be held for the period stipulated by ethics in the secure research data storage repository at Flinders University, managed by the Flinders University, Information and Digital Services (IDS) department

What is the archive plan if the chief investigator leaves the institution and no longer has access to the study data?

The chief investigator will apply to have academic status which will enable ongoing access to the data. If this is not provided the other investigators would have to approve his access

How will the study data be destroyed?

The study data will be securely erased from the secure archive repository under the management of the Flinders University, Information and Digital Services (IDS) department

Matching and sampling strategies:

Phase 1: We will aim to recruit 40 people with a sports betting addiction for the pilot study. Based on our case studies and the literature, the majority (80-90%) will be young males. As all participants will be offered the intervention there will be no need to match or stratify.

Phase 2: We aim to randomise 140 people with sports betting addiction equally to 2 groups. Some will have sports betting alone, others will have other forms of gambling. We will stratify based on sports betting alone and sports betting plus other forms of gambling.

A biostatistician will independently generate random sequences for each stratum using Stata version 11.1 software and delivered these to the Flinders clinical trials call centre of a centrally located hospital pharmacy. RAs, collecting and entering data and therapists administering interventions will not know in advance which treatment the next participant would receive.

Accounting for potential bias, confounding factors and missing information:

In phase 2 consecutive recruitment of larger sample (140) from anywhere in Australia where someone has access to the internet including rural and remote areas should minimize bias. Eligible individuals will be randomly assigned to 1 of 2 treatment groups with 1:1 allocation ratio before their pre-treatment assessment with a therapist. From the trial outset, randomisation will be blocked to increase the likelihood of equal group sizes, using a standard permutated block algorithm in which block sizes were randomly chosen from 2, 4, and 6 to protect concealment.

In this trial, therapists will know what treatment they are administering and participants will be provided with information that rationalises and describes their assigned therapy protocol. It is intended that participants are masked to the study hypothesis in order to help limit the likelihood for self-report bias. Participant information sheet will refer to treatments as “well known and commonly used psychological treatments”. To avoid contamination of masking, SGTS administration staff members will be instructed not to reveal specific treatment labels to any participants and therapists not to reveal the alternative treatment label.

Fidelity: All therapy sessions will be audio recorded and in phase 1 all sessions will be listened to by CIs Riley, Baigent and Battersby and rated using the adapted 10 item checklist which was developed based on the Cognitive Therapy Scale (CTS) which is an 11-item instrument with good reliability when used by experienced clinicians (Young & Beck, 1980), used for a previous SGTS study of CET vs Cognitive Therapy. (Smith et al). In phase 2 , 20% of sessions will be randomly selected from early, mid, and late study phases and checked for therapy fidelity.

Baseline differences will be corrected for if required and missing data will be handled by multiple imputation

Sample size and statistical or power issues – Make sure the size and profile of the sample to be recruited is adequate to answer the research question – please provide details:

Phase 2: In our sample size calculations, we assume a correlation between follow-up measures of r 0.7 (Frison & Pocock, 1992). Based on a type I error rate of 5%, power of 90%, two-tailed test, and a VGS standard deviation of 10.2 units (Smith et al., 2010), to detect a significant difference of 8% (i.e. 4.8 points on the scale) in mean VGS scores between the CET and control groups, 50 participants were required in each group. Given the treatment drop-out rate experienced in

the SGTS treatment programme (approximately 35%) we therefore needed to recruit 70 participants in each group of the study giving a total sample size of 140 participants.

How will you measure, manipulate and/or analyse the information collected?

Phase 1 and 2: The primary analysis will use all available data and follow an intent-to-treat principle to investigate any statistically significant differences in primary and secondary outcomes over time between both groups. Secondary analyses will be conducted based on 'as treated' and 'per protocol' approaches within a counterfactual framework using inverse probability weighting (IPW) (Hernan & Hernandez-Diaz, 2012). The IPW uses the inverse of the probability of being in the observed treatment group.

Generalised mixed-effects models will be used in the analysis of repeated measures for primary and secondary continuous and categorical outcomes. Fixed effects (time-invariant variables) in models were intervention group, time in continuous form (intervention period and follow-up), and interaction between group and time.

Finally, the proportion of participants who have VGS scores in the non-problem gambling range (<21) at 2, 6 or 12 month follow-up will be tested using Fisher's exact test.

Effect size statistics will also be produced for comparisons of mean observed scores (Cohen's d) (Cohen, 2013) and associations of nominal variables (Cramer's V or phi for 2 2 contingency table) (Cram er, 1946). For nonparametric between-group tests, the Manne Whitney statistic will be calculated as a measure of effect size (Conroy, 2012).

Phase 1: qualitative data -Semi-structured interviews with purposefully chosen (age above and below 20, those who improved/recovered/those who dropped out/did not recover) 6 intervention participants and 2 therapists to determine recruitment barriers and enablers, acceptability and feasibility and any improvements to the intervention or delivery and recruitment. Of particular interest will be the on-line and social media strategies used to recruit non help seeking sports betters. These interviews will be conducted by the RA using phone or videoconferencing with set open ended questions

Data linkage –what linkages are planned or anticipated?

No data linkage activities are planned.

What impact will a participant withdrawing have on the data and how will this be responded to?

Data already recorded from the participant will be retained (as per ethics requirements) but marked as not for use in the study.

Results, reporting, outcomes and future plans

Post approval monitoring and reporting

Once you have received ethics and governance authorisation for your research project, there are the following mandatory reporting requirements you must adhere to as per The National Statement chapter 5.5:

- Annual review – this is required annually for the life of the research on the anniversary of the approval date.
- Final report – this is required to be submitted on completion of the research.
- Amendments – any change to the approved protocol must be reported to the lead HREC.

Failure to submit the required reports is a breach of the NHRMC Australian Code for the Responsible Conduct of Research R17, R22, the National Statement chapter 5.5 and the terms and conditions of the ethical approval of the study. This failure to submit the required report may result in the ethics approval being withdrawn and the application closed.

The Office for Research has a Research Integrity webpage, which provides the channels in which all SALHN approved studies are monitored, plus self-monitoring tools for our researchers.

Please detail your plans for the return of the research results to the participants: The results of the pilot study will be simply to inform all participants that the data collection and study have been completed and acknowledgement that their contribution is important for preparation for the larger study, For the main study, we will inform the participants of any differences that may occur in between the participants receiving CET and the control intervention controls.
What are your plans for dissemination and publication of project outcomes: Results and a study summary will be provided by local SALHN and Flinders news communications, via local and on-line media and via publications in peer reviewed and open access journals and conference presentations nationally and COVID permitting internationally. No participants will be identifiable in any publication.
Please detail other potential uses of the data at the end of the project: The data itself will have no other use, however the results will be of use clinically to psychiatrists, psychologists and governments with Gambling help services, GPs and Beyond Blue
What are your plans for sharing and/or future use of data and/or follow-up research? i.e. anticipated secondary use of data: The deidentified data may be used by other researchers who wish to try other analytical techniques to possibly improve the classification accuracy
What is the project closure process? I.e. a final report will be submitted to the HREC, where the study data and/or samples will be stored? A final report will be submitted to the ethics committee. The data will be held for the period stipulated by ethics in the secure research data storage repository at Flinders University,

managed by the Flinders University, Information and Digital Services (IDS) department. data files stored in the Universities secure storage facilities (as above) for the stipulated timeframes