









BMJ Open Social norms and goal-setting interventions to promote responsible gambling in low-to-moderate online gamblers: protocol for a four-arm randomised controlled feasibility study

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ABSTRACT

Introduction Gambling is increasingly recognised as an important public health issue. Problem gambling is associated with highly negative impacts on physical, psychological and social well-being, not only for those who gamble but also for those around them. There has been a rapid expansion of internet gambling and attributes such as continuous play and instant rewards, and enhanced privacy may lead to a greater likelihood of gambling-related harms. In this randomised controlled feasibility study, we are testing (1) the acceptability and feasibility of three online responsible gambling interventions targeting people with low-to-moderate risk of online problem gambling and (2) the feasibility of a future full-scale randomised controlled trial (RCT) to test their effectiveness and cost-effectiveness.

Methods and analysis Four-arm randomised controlled feasibility study with qualitative substudy. One-hundred and forty UK residents with low-to-moderate risk of online gambling recruited via gambling operators and social media will be randomised (1:1:1:1) to either (1) goal setting, (2) descriptive norms messages (challenge perceptions of peer behaviours), (3) injunctive norms messages (challenge perceptions of peer attitudes) and (4) control (delayed intervention). Interventions will be delivered over 6 weeks and individually tailored. Outcomes, administered online, will be measured at baseline, 7 weeks, and 3 and 6 months post randomisation (including gambling risk behaviours and cognitions, anxiety and depression, quality of life, health use and productivity). Analyses will be descriptive, focusing on feasibility and acceptability of the interventions and study procedures. Telephone/online interviews, with a subsample of approximately 30 participants, will elicit experiences of participating in the study. Prespecified progression criteria will guide decisions around whether to progress to a definitive RCT.

Ethics and dissemination Ethical approval obtained from Bournemouth University Research Ethics Committee (reference number 33247). Participants will be given a participant information sheet plus a 'Key Facts' summary and will provide informed online consent. Findings will

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ We will test the relative acceptability and feasibility of injunctive and descriptive social norms in the context of online gambling.
- ⇒ We will use objective gambling data obtained from operators to validate participant self-reports of their gambling activity.
- ⇒ This study will use a mixed methods approach, enabling us not only to determine the feasibility and acceptability of study design, recruitment and randomisation procedures but also to explore experiences of participation in the intervention and the study.
- ⇒ Due to the nature of the interventions, blinding of participants will not be possible.
- ⇒ Participants will be self-selected.

be published in peer-reviewed journals and presented at conferences and public engagement events.

Trial registration number ISRCTN37874344.

INTRODUCTION

Gambling for money is a popular leisure activity worldwide but can become problematic for some. Problem gambling is detrimental to psychological and physical well-being and is associated with harmful personal and societal costs.^{1–5} Thus, gambling is an important public health concern.^{6 7}

Internet gambling, which facilitates high accessibility, anonymity, appealing design mechanics, immersive interface and ease of spending, is associated with higher risk and severity of gambling problems than land-based gambling.^{8–10} Internet gamblers are more likely to make riskier bets,¹¹ consume more alcohol and illicit drugs,¹² face higher debt levels,¹³ and are less likely to recognise

problems¹⁴ than land gamblers. Internet gambling enables rapid continuous play, instant rewards, gambling while intoxicated and enhanced privacy, which may undermine a gambler's ability to maintain control and increase proclivity to chase losses.^{15 16} Given the rapid expansion of internet gambling, the scale of problem gambling behaviours is at risk of increasing, with the current UK gambling prevalence estimated at 0.5%.¹⁷ Among adolescents, 5% of teenagers in Europe are estimated as engaging in problem gambling behaviours.¹⁸ As national lockdowns due to COVID-19 have led to rises in online gambling in some at-risk groups¹⁹ and help-seeking is rare among individuals with low or moderate risk of problem gambling,²⁰ interventions to prevent gambling-related harms are urgently needed.

While a recent framework highlighted the need for behavioural science approaches and multiple stakeholder involvement to minimise gambling harms,⁸ research focused on guiding evidence-based policies or practice is limited. Recent reviews on strategies and interventions for gambling-related harm²¹⁻²³ revealed the narrow scope of existing public health interventions and poor quality of current evidence for effectiveness, underlining the need for further research.

Many risk factors for gambling are heightened when using mobile (eg, smartphones and tablets) and supplementary devices (eg, gaming consoles and interactive televisions).²⁴ Gamblers who use mobile devices typically have higher average bets and longer, more frequent sessions than computer users.²⁵ Given that 95% of the UK population aged 16+ own a smartphone²⁶ and minimal user effort is required, mobile phone-based interventions to prevent or reduce gambling harms will likely be low cost, with wide reach. Text messaging interventions have not reduced gambling severity in problem gamblers^{27 28} but may be more effective as a preventive intervention for individuals with low-to-moderate risks of online problem gambling.²⁷ Potential population-level benefits would be considerable, given estimated costs of up to £1.27 billion/year nationally from problem gambling.²⁹ Although attrition is a significant issue for mobile app interventions, reducing the number of points where it might occur can help to minimise it.³⁰

Interventions involving goal setting have shown robust effects on behaviour change in numerous contexts.^{31 32} Goal setting is optimally effective when goals are public, set face-to-face in combination with behavioural monitoring from another person, measurable and observable.³³ A brief in-person goal-setting intervention focusing on gambling expenditure³⁴ reduced spending among individuals with moderate risk and problem gambling but not non-problem or low-risk gambling. However, this intervention was delivered in one 15 min session. Repeated sessions are more effective than single sessions in enabling sustained behaviour change.³⁵ Mobile devices offer possibilities for tracking and sharing goals and for tailored feedback, core to goal-setting theory.^{36 37}

Evidence suggests interventions targeting social norms (rules and standards understood by group members that guide or constrain social behaviours³⁸) could work well in promoting responsible gambling (RG).³⁹ Social norms comprise 'descriptive' (perceptions of peer behaviours) and 'injunctive' (perceptions of peer attitudes) norms.⁴⁰ Social norm interventions operate on the basis that individuals typically believe their peers behave in riskier ways and hold riskier attitudes than is actually the case, misperceptions that have been documented extensively around alcohol and substance use in young adults.⁴¹⁻⁴³ Technology can be used to deliver population-level social norm campaigns, automating the process of creating personalised messages and delivering them to the intended recipients.⁴⁰ The social norms approach is one of the most cost-effective population-level methods of reducing alcohol harms on American college campuses.⁴⁴

To date, the limited randomised controlled trials (RCTs) assessing the effectiveness of social norms in managing gambling behaviours have mainly focused on university students. For example, a single exposure to a personalised norms message reduced risky gambling behaviour and misperceptions at 3-month follow-up.⁴⁵ In contrast, a recent systematic review and meta-analysis⁴⁶ found no evidence of reductions in gambling frequency. However, this review included only adults with problematic levels of gambling. Many social norm interventions are delivered at a population level and aimed at individuals below the threshold for clinical diagnosis of a harmful behaviour.³⁹ Further, most social norm intervention studies have focused on descriptive norms. It remains unclear whether injunctive norm interventions can change behaviour or attitudes more effectively than descriptive norm interventions.⁴⁰ A recent meta-analysis recommends that, given their brevity and low cost, future research both investigates the utility of social norm interventions in alerting people to problem behaviour as a first step to facilitate motivation and consideration of behaviour change in those at lower risk of harms and assesses the cost-effectiveness of such interventions.⁴⁶

As gamblers often hide the true extent of their behaviour from others,⁴⁷ preventive programmes maintaining privacy and anonymity will likely be well received. While previous studies targeted prevention and early intervention strategies by focusing on RG tools, pop-up messages⁴⁹ and problem gambling education materials,⁵⁰ interactive messages involving goal setting and social norms have not been tested in relation to online gambling. Individuals who engage in problem gambling place higher confidence in and believe they have greater control over their bets than non-problem gamblers.^{51 52} These cognitive distortions are associated with both emotional distress and greater problem gambling severity.⁵ Hence, self-guided personalised digital approaches challenging these beliefs may facilitate positive changes in gambling behaviours and also emotional well-being. Many internet-based interventions rely on self-reported gambling behaviour, which is susceptible to

social desirability bias^{53 54} and inaccurate reporting.^{55–57} As a first step in tackling this problem, validation of self-reported gambling behaviour via player data obtained directly from gambling operators is needed.

Aims and objectives

The aims of this multiarm randomised controlled feasibility study are to assess (1) the feasibility and acceptability of three RG interventions (goal setting, descriptive norm messages and injunctive norm messages) and (2) the feasibility of conducting a full-scale effectiveness and cost-effectiveness superiority trial testing the aforementioned interventions, which aim to reduce the likelihood of individuals moving from low or moderate risks of problem gambling to problem levels of gambling.

The specific objectives are to:

- ▶ Assess the acceptability and feasibility of key aspects of study design, recruitment and randomisation processes, the data collection strategy and the respective interventions.
- ▶ Estimate eligibility, participation and drop-out rates (from intervention and/or study) and adherence to the three interventions (number of goals set and number met (goal-setting arm) and number of social norm messages read (social norms arms)).
- ▶ Explore participants' experiences of participating in the trial, receiving the interventions and completing the outcome measures, via qualitative interviews (telephone/video conference/secure messaging app (WIRE)) and participant feedback via WIRE about intervention messages.
- ▶ Determine whether a social norms approach to promoting RG is acceptable to individuals at low-to-moderate risk of online problem gambling, as measured by uptake of and adherence to the interventions and feedback from the qualitative interviews.
- ▶ Assess the acceptability and suitability of the outcome measures and inform the selection of the primary outcome for a future full-scale RCT.
- ▶ Collect data on the variability of outcome measures to inform a sample size calculation for a larger trial and obtain preliminary effect size estimates.
- ▶ Provide preliminary information about levels of gambling at which the intervention is most beneficial.
- ▶ Pilot questions about primary healthcare use and productivity levels in preparation for an economic evaluation in a future definitive RCT.

METHODS AND ANALYSIS

Design

This is a 26-week, four-arm, parallel group, pragmatic randomised controlled feasibility study with a nested qualitative study. Participants will be randomised to one of four arms (goal setting vs descriptive norms vs injunctive norms vs control) in a 1:1:1:1 ratio (figure 1). Those randomised to the control arm will have the option of receiving their choice of one of the three interventions at the end of the feasibility study (6

months following randomisation). This design has the potential to minimise the impact of disappointment those allocated to a non-intervention group might experience. A nested qualitative interview study will provide insights into experiences of participating and acceptability of study processes, the respective interventions and outcome measures.

We will report the study and findings in line with the Consolidated Standards of Reporting Trials (CONSORT) extension for randomised controlled pilot and feasibility studies,⁵⁸ the CONSORT extension for reporting of multiarm trials⁵⁹ and for psychological interventions,⁶⁰ the CONSORT ehealth guidelines,⁶¹ and guidelines for describing interventions⁶² and reporting of qualitative research.^{63 64} The Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines will be followed.⁶⁵

The study is now in follow-up. The first participant was recruited on 5 May 2021 to complete the prebaseline social norm questions. The first participant was randomised on 26 January 2022 and the final participant on 17 August 2022. The final 6-month follow-up questionnaires are scheduled for administration on 16 February 2023.

Patient and public involvement (PPI)

Two people with former gambling problems were involved in developing this protocol, including providing feedback about the study questionnaires. People with a former gambling problem and those who gamble at low-to-moderate levels will provide input throughout the study including developing the interview topic guide, interpretation and dissemination of findings. We will follow national PPI standards⁶⁶ and record outcomes and impacts of PPI.⁶⁷

Sample size considerations

As this is a feasibility study, sample size considerations relate primarily to determining the feasibility of progressing to a definitive trial. Following Lewis *et al*'s recommendations,⁶⁸ we based our sample size on ensuring adequate power to evaluate signals for progression across our three prespecified progression criteria relating to (1) study uptake, (2) study retention and (3) intervention adherence. This involves using a multicriterion hypothesis testing approach (for a detailed explanation, see Lewis *et al*⁶⁸) focused around the traffic light system convention for progression criteria.⁶⁹ Using the look-up grid Lewis *et al*⁶⁸ provided (to meet 90% power with one-tailed 5% alpha), of our three specified progression criteria, intervention adherence (criterion 3) requires the largest sample size (34 per arm; see table 1). For convenience, we rounded this up to 35 per arm, meaning 140 participants overall, in line with recommendations suggesting 35 per arm is sufficient to estimate key parameters in feasibility and pilot studies and adequate to estimate the SD of a continuous outcome.⁷⁰

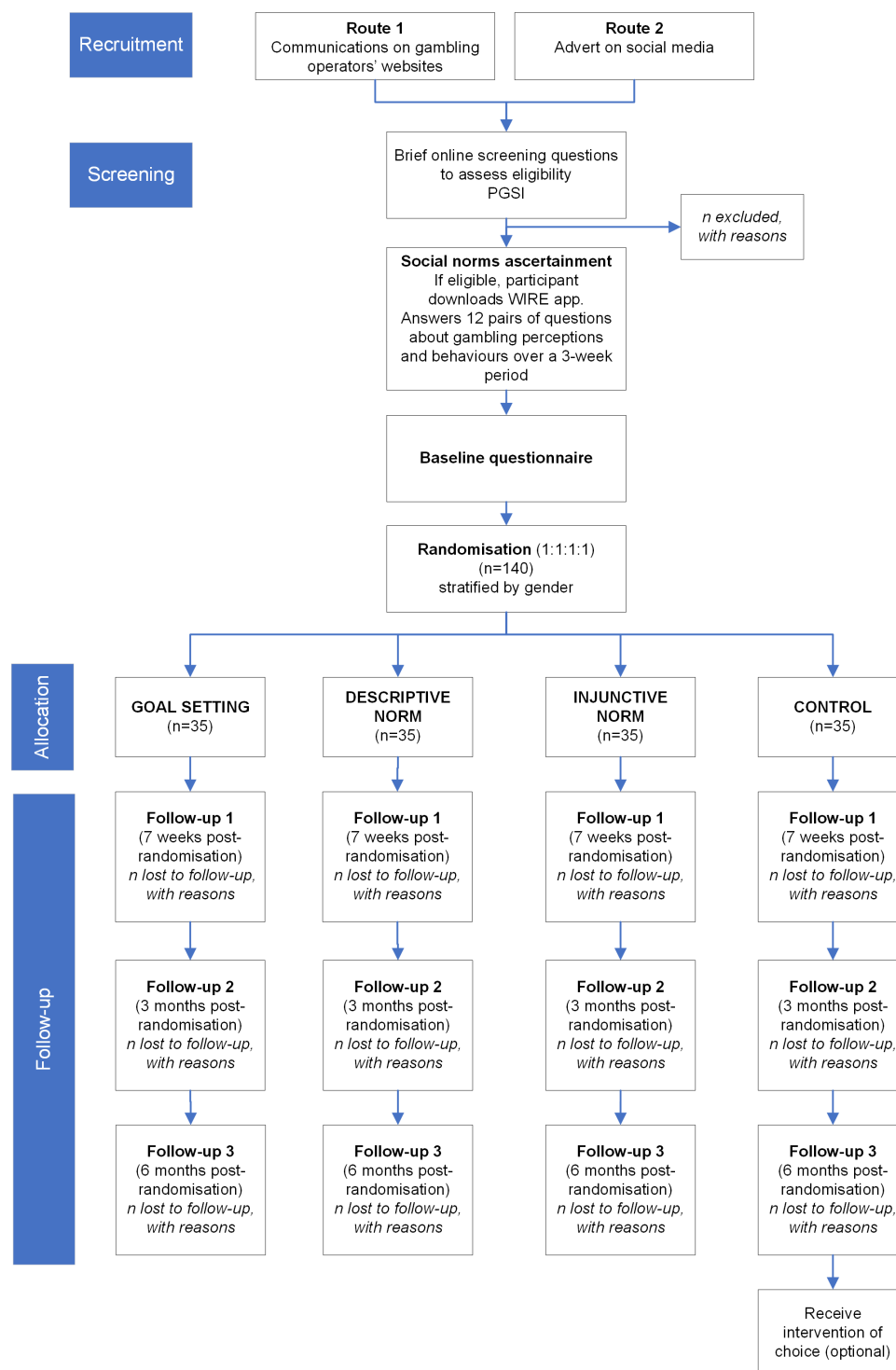


Figure 1 Consolidated Standards of Reporting Trials diagram. PGSI, Problem Gambling Severity Index.

With a total sample of 140, the recruitment rate will be estimated with a precision of $\pm 6\%$ (assuming a recruitment rate of 50%), and we will be able to estimate a drop-out rate of 30% to within a 95% CI of $\pm 8\%$. A questionnaire return rate of 80% would mean availability of data at baseline and follow-up for 112 participants with the return rate estimated with precision of $\pm 7\%$.

Participants and eligibility criteria

We aim to recruit 140 participants in total. Eligibility criteria are provided in [box 1](#).

Study setting, screening and recruitment

The study will be advertised via communications on UK-licensed gambling operators' websites and social media. Individuals will be asked to click on a link which will direct them to a study information page with the participant information sheet (see online supplemental file 1) and

Table 1 Progression criteria with sample size requirements

Outcome	Measure	Green: proceed to RCT	Amber: consider possible improvements	Red: do not proceed	Sample size required (from Lewis <i>et al</i> 's lookup grid) ⁶⁸
Uptake	% randomised of those screened as eligible	≥35%	20%–34%	<20%	78 screened
Retention	% of participants retained at 6-month final follow-up	≥70%	50%–69%	<50%	55 randomised
Adherence	% of participants with ≥60% adherence to intervention (adherence defined as having read at least four of six messages in social norms arms or setting at least four of six goals in goal-setting arm)	≥75%	50%–74%	<50%	34 per intervention arm

RCT, randomised controlled trial.

consent (agreement) form (see online supplemental file 2). Those interested in participating who have provided informed consent will be asked to complete an online screening questionnaire via the Qualtrics survey platform (Qualtrics, London, UK) to assess whether they fulfil the inclusion criteria. Eligible participants will be informed via email, resent the participant information sheet and a 'Key Facts' summary and provided with instructions to download WIRE (a secure messaging app) (used for prebaseline social norm data collection and intervention delivery). Ineligible participants will be informed via email and provided with information about the National Gambling Helpline.

Social norm establishment (prerandomisation)

This phase will take place with all trial participants via the WIRE app before randomisation and will involve establishing baseline gambling behaviours (eg, frequency of gambling and typical amount gambled) and attitudes (eg, feelings of regret and willingness to seek professional help), as well as perceptions of peers' gambling behaviours and attitudes. Participants will be sent 12 pairs of questions assessing their behaviours and perceptions towards gambling over a 3-week period, via the WIRE app. Administration will be spaced across 3 weeks to reduce the risk that prompting a participant to consider one norm may influence their response to a subsequent norm question.⁷¹

In addition to the prebaseline social norms assessment, an online survey will be undertaken with a separate sample of 350 people (not part of the randomised feasibility

study) who live in the UK and gamble frequently (at least once/week). They will be asked questions about their gambling behaviours, attitudes and perceptions of peers' gambling behaviours and attitudes. Participants will be recruited via an online platform (Prolific) where the survey will be hosted. These data will inform the content of the social norm arms messages.

Randomisation, concealment of allocation and blinding

Randomisation will take place after participants have completed the 3-week social norm establishment (prebaseline) and baseline questionnaires. To ensure adequate allocation concealment, sequence generation and randomisation will be undertaken using Sealed Envelope, a centralised, independent web-based randomisation service (<https://www.sealedenvelope.com>). Once a participant completes and returns the baseline questionnaires, the study manager will randomise them, in an equal ratio, to one of the four study arms via Sealed Envelope. Permuted randomised blocks will be used and randomisation stratified by gender (male/female/prefer not to say or other).

Given the nature of the interventions, participants cannot be blinded to allocation. The study manager will screen and enrol participants, deliver intervention materials and send out links for the online follow-up questionnaires, and so will not be blinded to allocation. All outcome measures will be self-completed online. The study data will be analysed with no access to information about allocation.

Interventions

All three interventions (goal setting, descriptive norms and injunctive norms) will be delivered via a secure messaging mobile phone application (app) called WIRE and will run for 6 weeks. To enable comparison with the broader literature, [table 2](#) specifies the behaviour change techniques (BCTs) used in the interventions according to the BCT taxonomy (v1).³⁵

Goal setting

Participants will be provided with advice about how to set specific, measurable, attainable, realistic and time-bound goals, first via a video (which can be replayed at any point during the intervention), then via text message. We will ask participants to create a weekly goal relating to their gambling activity (money-based goals will be

Box 1 Eligibility criteria

Inclusion criteria

- ⇒ Age 18 years or above.
- ⇒ Resident in the UK.
- ⇒ Gambles online for a minimum of one session per week on a UK gambling operator's website (assessed via self-report).
- ⇒ Sufficient English language ability to complete the questionnaires and engage with the interventions.
- ⇒ Owns a smartphone.
- ⇒ Willing to download WIRE.

Exclusion criteria

- Score on the PGSI⁸¹ indicative of problem gambling (PGSI score ≥8).

PGSI, Problem Gambling Severity Index.

Table 2 BCTs used in the interventions

Intervention	BCT
Goal setting	Goal setting (behaviour) (1.1) Goal setting (outcomes) (1.3) Action planning (1.4) Review behaviour goals (1.5) Social reward (10.4)
Descriptive norms	Social comparison (6.2)
Injunctive norms	Social comparison (6.2) Information about others' approval (6.3)
BCT, behaviour change technique.	

recommended) and one to three action plans for the goal, and to share these goals with the study manager via WIRE. At the end of each week, we will ask participants to provide their gambling data for that week via WIRE.

Participants will be asked to create six goals in total over the 6-week period. Each week we will ask participants if they have achieved the goal they set. Those who have partially/completely achieved a goal will be given positive feedback. Those who have not met a goal will be encouraged to revise it to something more manageable. If participants do not create or share a goal, they will be sent a maximum of two reminders per week.

Social norm interventions

In both social norm interventions, participants will be sent brief weekly messages (six in total) via WIRE based on their social norm prerandomisation data and tailored to their age and gender. Participants will be invited to provide feedback about each message.

Descriptive norm intervention

Messages will challenge any misperceptions participants may have around norms of gambling behaviours; for example, 'You told us you gamble 7 days a week and that you think a typical person who gambles does so five times a week. Most men (61%) aged 35 or over gamble no more than 2 days a week.'

Injunctive norm intervention

Messages will challenge any misperceptions participants may have around norms of gambling attitudes; for example, 'You told us that you sometimes feel you should cut down on your gambling. Most women (60%) aged 18 to 34 very rarely feel that they should cut down on their gambling.'

Control arm

Participants in this arm will not receive any of the three interventions but will be offered the option of receiving their choice of intervention (goal setting/descriptive norms/injunctive norms) after the final follow-up (6 months post randomisation).

Participants in all arms will have optional access to RG tools made available by operators they are signed up with, including deposit limits and self-exclusion options.

Participants will be asked at baseline if they use any RG tools and use of RG tools will be explored in the qualitative interviews.

Outcome measures and data collection

Study data will be collected and managed using the Qualtrics survey platform and the WIRE application. One aim of this feasibility study is to inform selection of outcome measures for a subsequent full trial. We therefore include a broad range of outcome measures to explore acceptability and completion rates. Questionnaires will be administered online at baseline (including demographic and gambling information) and at 7 weeks, 3- and 6 months post-randomisation (see table 3 for details of self-reported outcomes and administration schedule). If participants do not complete questionnaires, they will be sent two email reminders.

Two former problem gamblers reviewed all outcome measures. One, in addition to positive feedback, suggested asking if participants play online games requiring payment to level up. We added a question about this to the baseline questionnaires. The second commented that the ICEpop Capability Measure for Adults (ICECAP-A)⁷² questionnaire items seemed strange. We will examine completion rates for the ICECAP-A and explore its acceptability and relevance in the qualitative interviews.

We will ask about age category, gender, household living arrangements, education, ethnicity, employment status and narcissism, an exploratory outcome (using the Narcissistic Admiration and Rivalry Questionnaire).⁷³ We will ask about type of gambling activities undertaken (eg, sports betting, casino games, etc), device used, typical gambling location, number of online accounts and use of RG tools.

Participants will be offered £55 in Amazon vouchers for completion of study outcome measures (£5 following completion of the social norm prebaseline questionnaire, £10 following completion of the baseline questionnaires, £20 following completion of the 7-week follow-up questionnaires, £10 following completion of the 3-month follow-up questionnaires and £10 following completion of the 6-month follow-up questionnaires).

In each online questionnaire pack, participants will be given a link to the Participant Information Sheet, which contains information about the National Gambling Helpline and a link to GamCare support, if required.

Outcomes

Our primary outcomes are feasibility and process outcomes related to determining the feasibility and acceptability of study design, recruitment and randomisation, the data collection strategy, methods and interventions. These are summarised in table 4.

Secondary outcomes will be completed by all participants and will include self-reported outcome measures related to gambling risk behaviours, anxiety and depression, gambling cognitions, capability, well-being and

Table 3 Schedule of enrolment, interventions and assessments

Timepoint	Study period											
	Enrolment	Baseline	Allocation	1	2	3	4	5	6	Follow-up (time post allocation)		
	-t ₁	0	0	1	2	3	4	5	6	7 w	3 m	6 m
Enrolment												
Eligibility screen	X											
Informed consent	X											
Social norms ascertainment	X									X		X
Allocation			X									
Interventions												
Descriptive norms												
Injunctive norms												
Goal setting												
Assessments												
Demographics		X										
PGSI (9 items)*	X	X								X	X	X
NARQ (18 items)		X										
GRCS (23 items)		X								X	X	X
PHQ-8 (8 items)		X								X	X	X
GAD-7 (7 items)		X								X	X	X
EUROHIS-QOL (8 items)		X									X	X
EQ-5D-5L (5 items)		X									X	X
ICECAP-A (5 items)		X									X	X
Primary care health use		X									X	X
Productivity		X									X	X

Social norms ascertainment based on ⁸² PGSI, ^{81 83} NARQ, ⁷³ GRCS, ⁸⁴ PHQ-8, ⁸⁵ GAD-7, ⁸⁶ EUROHIS-QOL, ⁸⁷ EQ-5D-5L ⁷⁵ and ICECAP-A. ⁷²

*Using a 1-month recall period as used by others. ⁸³

EQ-5D-5L, EuroQoL Five Dimensions Five Levels; EUROHIS-QOL, European Health Interview Survey–Quality of Life; GAD-7, Seven-Item Generalised Anxiety Disorder Questionnaire; GRCS, Gambling-Related Cognitions Scale; ICECAP-A, ICEpop Capability Measure for Adults; NARQ, Narcissistic Admiration and Rivalry Questionnaire; PGSI, Problem Gambling Severity Index; PHQ-8, Eight-Item Patient Health Questionnaire.

quality of life (see table 3). We will also collect information about adverse events (AEs) (see separate section).

Feasibility economic component

We will pilot resource use questions asking participants how many contacts they have had with general practitioners (GPs) or nurses in the past 3 months (including virtual, face-to-face and telephone) and whether gambling was mentioned during these contacts.

We will pilot a self-report measure of productivity based on an existing measure ⁷⁴ that includes questions regarding (1) number of days of sick leave due to gambling/gambling-related health issues (past month), (2) number of days at work where productivity was perceived to be <50% of usual levels and (3) extent to which participants feel non-work daily activities have been affected by gambling/gambling-related health issues (both past 3 months). We will also pilot administration of the EuroQoL Five Dimensions Five Levels (EQ-5D-5L) ⁷⁵ and the ICECAP-A. ⁷²

Nested qualitative study

The study researcher will conduct approximately 30 qualitative semistructured telephone/video conference interviews: eight per intervention arm (post 3-month follow-up) and six with control arm participants (at the end of the study). Participation in the qualitative substudy will be optional (see Participant Information Sheet (PIS) and consent form (online supplemental files 3,4)). Participants will be purposively sampled for diversity of demographic characteristics, PGSI baseline scores and (intervention arms only) engagement with the interventions. Interviews will elicit participants' experiences of the interventions and study participation and processes. A flexible topic guide will allow adaptations in response to topics that emerge during the interviews. Interview participants will be offered a £20 Amazon voucher.

Analysis

Quantitative

As this is a feasibility study focused on estimating key feasibility parameters, analyses will be mainly descriptive. ⁷⁶ A CONSORT diagram ⁷⁷ will present proportions eligible, enrolled, randomised and lost to follow-up. Data related

Table 4 Feasibility and process outcomes

Feasibility objective	Outcomes (and how measured)
Assess acceptability and feasibility of key aspects of study design, methods and study interventions	Eligibility, recruitment and retention <ul style="list-style-type: none"> ▶ Number of participants screened, eligible, enrolled and randomised (study records and logs). ▶ Number of participants lost to follow-up (with reasons, if known) (study records).
	Outcome measures <ul style="list-style-type: none"> ▶ Response rates and levels of missing data (overall and item-level completion rates). ▶ Acceptability and relevance (from participant interviews).
	Primary care health use and productivity questions <ul style="list-style-type: none"> ▶ Levels of missing data. ▶ Acceptability and relevance (from participant interviews).
	Study design <ul style="list-style-type: none"> ▶ Acceptability of control group (participant interviews).
	Study interventions <ul style="list-style-type: none"> ▶ Appropriateness of goals set on WIRE (goal setting arm). ▶ Acceptability of social norms interventions (feedback via WIRE). ▶ Acceptability of interventions (participant interviews). ▶ Adherence: number of intervention sessions completed based on whether participants have opened and/or read the message (social norms messages) or set a goal (goal-setting arm).
	Self-reported gambling data (goal-setting arm only) <ul style="list-style-type: none"> ▶ Proportion of participants who share data at each assessment and format supplied.
	Objective player data <ul style="list-style-type: none"> ▶ Proportion of participants for whom data are obtained from gambling operator.
Inform selection of primary outcome measure for a definitive RCT	<ul style="list-style-type: none"> ▶ Response rates and % missing data of outcome measures. ▶ Feedback from participant interviews. ▶ Preliminary effect size estimates.
Inform sample size of a future RCT	<ul style="list-style-type: none"> ▶ SDs of continuous outcomes at 6 months follow-up. ▶ Study recruitment and attrition rates.

RCT, randomised controlled trial.

to recruitment, attrition, outcome measures, process measures, questionnaire return rates and adherence to the interventions will be presented using descriptive statistics (with 95% CIs). SDs of potential primary outcome measures will be estimated. We will summarise and report rates and patterns of missing questionnaire data to inform the selection of outcomes and administration strategy for a full trial. We will also develop and test our data analysis procedures, with the aim of informing the statistical analysis plan for a full trial. Preliminary estimates of effect size (with 95% CIs) for potential primary outcome measures will be calculated to inform the plausibility of the effect sizes used in future sample size calculations.

We will summarise primary care contacts with GPs and nurses using descriptive statistics and will derive QALY estimates (with 95% CIs) from EQ-5D-5L utility scores.

Qualitative

Data will be analysed using thematic analysis, following Braun and Clarke.^{78 79} We expect 30 interviews will be sufficient to reach saturation. Interviews will be coded by one researcher and a minimum of 2 interviews per arm second coded by another researcher.

Trial and data management

The chief investigator (CI) (JM) will be responsible for overall study conduct. The study management team, led by the CI, will meet at least monthly to review and monitor research conduct and address issues as they arise.

All personal data collected during the study will be handled, stored and protected in accordance with the

UK Data Protection Act (1998) and the General Data Protection Regulations (2018). All participants enrolled in the study will be allocated a unique study identification (ID). The document linking IDs with personal details will be password-protected and stored on a Bournemouth University secure server. Data will be anonymised and only accessible to authorised staff working on the study. The sponsor/host institution will be given access on request for monitoring and inspection purposes.

Data processing, management, validation and quantitative analysis activities will be conducted in accordance with Bournemouth University Clinical Research Unit standard operating procedures to ensure a clear audit trail and that relevant regulatory governance requirements are met. All data will be stored on a secure backed-up university server. Quantitative data will be exported from Qualtrics to a password-protected (SPSS V.28) database, plausibility data checks carried out (eg, range checks) and the database then closed to further changes, prior to analysis. All study documentation will be kept for at least 10 years after publication of study data in line with Bournemouth University policy. Digital audio recordings of interviews will be deleted once the anonymised transcripts are finalised.

Reporting of AEs

This is a low-risk study involving members of the general public who gamble, excluding those with PGSI scores indicative of problem gambling. We do not envisage any study-related serious AEs.

To help inform AE recording and reporting in a potential future definitive trial, the study manager and other research team members will inform the CI of any concerning communications or potential AEs received or reported via WIRE/email or during interviews. The CI will discuss these with two core research team members (EA-C, a health psychologist, and ST), then offer advice to the wider project team. The CI will assess an AE to establish if it is serious according to the National Research Ethics Service definition. If not defined as serious, the AE will be recorded on a case report form and stored in the site file, and the participant will be followed up as appropriate and signposted to relevant support, if necessary. Reporting of related and unexpected serious AEs (which we consider highly unlikely) would follow the same timelines as the Health Research Authority (email notification to university ethics committee within 15 days and notification to the study sponsor within 24 hours).

Progression criteria

To guide decisions about whether a full RCT is feasible and warranted, we have specified three progression criteria (recruitment, retention and intervention adherence) based on a traffic light system⁶⁹ (green, proceed; amber, consider possible improvements; red, do not proceed; see [table 1](#)). We will also consider the secondary outcomes and qualitative interview data.

Ethics and dissemination

This study has been approved by Bournemouth University Faculty of Science and Technology Ethics Committee (ref 33247, approved 11 September 2020). Participants will give informed consent online after reading the participant information sheet. We will comply with the Declaration of Helsinki principles and the International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines.

Findings will be disseminated via peer-reviewed journal articles, reports, conference presentations and public engagement events.

Anonymised quantitative data will be publicly stored in Bournemouth University's online data repository, BORDAR (<https://bordar.bournemouth.ac.uk/>).

DISCUSSION

This feasibility study of social norms and goal setting to promote responsible online gambling will identify the conditions necessary for a definitive trial, including requirements for successful study design and data collection. If progression criteria are met/met within reasonable limits and the interventions and study processes appear acceptable and feasible, we will proceed to a definitive trial of effectiveness and cost-effectiveness of goal setting and social norms compared with usual care for those who gamble online at low-to-moderate levels.

This feasibility study has several limitations. First, given the nature of the interventions, blinding participants to

allocation will not be possible. Also, as the study manager will screen and enrol participants, deliver intervention materials and send out links for the online follow-up questionnaires, they will not be blinded to allocation. However, this is unlikely to significantly impact findings as all outcome measures will be self-completed online. Second, participants will be self-selected, increasing the possibility of selection bias. However, as we aimed to recruit via the general population, the only way to provide a more representative sample would be for gambling operators to embed the study into their platforms.

Given the rapid expansion of internet gambling, which is associated with higher risk for and severity of gambling problems than land-based gambling,^{9 10} increases in gambling among adolescents¹⁸ and increases in those with problem gambling behaviours in the general population,¹⁷ interventions to prevent gambling-related harms are urgently needed. However, as stigma around gambling leads to many hiding their gambling from significant others,⁸⁰ the three interventions in this feasibility study were designed to enable individuals to access anonymous online support.

The use of social norms in the context of online gambling is novel as is the use of objective player data (provided by operators) to validate self-reported gambling data. This is a first step towards basing future interventions directly on live data rather than self-report, which will enable individuals to receive more accurate feedback about their gambling. Given that numbers of gamblers and those with problem levels of gambling continue to rise with the shift to online gambling following the COVID-19 pandemic, interventions to promote responsible online gambling are needed more than ever.

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Contributors EA-C and JM conceived the study and wrote the initial grant application. JM designed the social norms arms of the trial and EA-C the goal-setting arm. ST provided methodological advice and input. EA-C, ST and JM led the drafting of the paper. RB-E and RW contributed to the writing of the paper. SH, EB and KP provided feedback on drafts. EA-C and ST contributed equally to this paper and are joint first authors. All authors critically reviewed and approved the final version.

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Competing interests Authors are coinvestigators or employed research staff on the EROGamb 2.0 project funded by GambleAware for which this feasibility study is a work package. JM is a member of the Gordon Moody Board of Trustees

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