Data-informed behaviours and responsible gambling

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
30/10/2020		[X] Protocol		
Registration date 19/11/2020 Last Edited	Overall study status Completed Condition category	Statistical analysis plan		
		Results		
		Individual participant data		
16/09/2024	Other	[X] Record updated in last year		

Plain English summary of protocol

Current plain English summary as of 25/02/2022:

Background and study aims

Over 400,000 individuals in the UK identify as problem gamblers, a number that is rapidly expanding given the increasing popularity of online gambling. At the same time, it is rare that those affected seek treatment. Currently, the point at which someone shifts from being a social gambler to a problem gambler is not known. The stigma around gambling means gamblers rarely seek treatment and prefer anonymity, hence online interventions are likely to be well-received. The aim of this study is to test the feasibility and acceptability to gamblers of online interventions using feedback, SMART (Specific-Measurable-Attainable-Realistic and Time-Bound) goal-setting, and social norms. It will also help us to find out whether a large-scale trial is possible and if so, help us to plan it.

Who can participate?

Adults aged 18 or over in the UK who place bets at least once a week

What does the study involve?

Participants will be randomly allocated to one of 4 groups:

- 1. Goal setting intervention
- 2. Descriptive norm messages (information about how other people gamble)
- 3. Injunctive norm messages (information about other people's attitudes to gambling)
- 4. Wait-list control group (no additional treatment until end of study)

All three groups will take part in the intervention for 6 weeks over the internet via a secure messaging mobile phone application called WIRE, but the content of the programme will be different for each group. Participants in the goal setting group will be asked to share their previous week's gambling-related data with the researchers during the intervention. In all groups, we intend (with participants' permission) to obtain participant gambling-related data from gambling operators at the end of the study.

Around 10-12 participants from each of the four groups will be invited for an interview after the intervention to find out about their experiences of the interventions and taking part in the study. We will also interview around 6 participants from the wait-list control group at the end of

the study. Participants who take part in an interview will receive a £20 voucher. Outcome measures will include self-reported mood, beliefs about gambling, quality of life, wellbeing, primary care health use, and productivity.

What are the possible benefits and risks of participating?

The main benefit is that all participants will have the opportunity to receive an intervention over the WIRE app (if they are assigned to the control group they will be invited to receive their choice of one of the three interventions once the study has finished) which makes it possible to receive support over geographical distances and at times chosen by the participant. Possible risks are that being in the control group might cause negative impacts on wellbeing as participants could feel they are missing out. However, as noted, they will be offered the intervention of their choice at the study end. Participants will be offered vouchers for completing questionnaires during the study (up to a value of £50).

Where is the study run from?

Department of Psychology, Bournemouth University (UK)

When is the study starting and how long is it expected to run for? From June 2020 to February 2023

Who is funding the study? GambleAware (UK)

Who is the main contact?
Dr Emily Arden-Close
eardenclose@bournemouth.ac.uk

Previous plain English summary: Background and study aims

Over 400,000 individuals in the UK identify as problem gamblers, a number that is rapidly expanding given the increasing popularity of online gambling. At the same time, it is rare that those affected seek treatment. Currently, the point at which someone shifts from being a social gambler to a problem gambler is not known. The stigma around gambling means gamblers rarely seek treatment and prefer anonymity, hence online interventions are likely to be well-received. The aim of this study is to test the feasibility and acceptability to gamblers of online interventions using data-driven feedback, SMART (Specific-Measurable-Attainable-Realistic and Time-Bound) goal-setting, and data-driven social norms. . It will also help us to find out whether a large-scale trial is possible and if so, help us to plan it.

Who can participate?

Adults aged 18 or over in the UK who place bets at least once a week

What does the study involve?

Participants will be randomly allocated to one of 4 groups:

- 1. Goal setting intervention
- 2. Descriptive norm messages (information about how other people gamble)
- 3. Injunctive norm messages (information about other people's attitudes to gambling)
- 4. Wait-list control group (no additional treatment)

All three groups take part in the study over the internet for 6 weeks, but the content of the programme is different for each group. All participants will be asked to share their previous

week's gambling-related data with the researchers after the baseline questionnaire and after 6 weeks, 3 months, and 6 months. Data will include self-reported mood, beliefs about gambling, quality of life, wellbeing, heath use, and loss of productivity.

What are the possible benefits and risks of participating?

The main benefit is that all participants will have the opportunity to receive an intervention over the internet (if they are assigned to the control group they will be invited to receive an intervention once the study has finished) which makes it possible to receive support over geographical distances and at times chosen by the participant. Possible risks are that being in the control group might cause negative impacts on wellbeing as participants could feel they are missing out. However, they will be offered the intervention of their choice at the study end.

Where is the study run from?

Department of Psychology, Bournemouth University (UK)

When is the study starting and how long is it expected to run for? From June 2020 to November 2022

Who is funding the study? GambleAware (UK)

Who is the main contact?
Dr Emily Arden-Close
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Contact information

Type(s)

Scientific

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Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

A 4-arm randomised controlled feasibility study of online social norms and goal setting for promoting responsible gambling in low to moderate gamblers

Study objectives

Current study hypothesis as of 25/02/2022:

- 1. Assess the acceptability and feasibility of key aspects of study design, randomisation and recruitment processes
- 2. Estimate recruitment and retention rates
- 3. Assess the suitability of the outcome measures and inform the selection of the primary outcome for a future full-scale RCT
- 4. Explore participants' experiences (including barriers and facilitators) of participating in the study, receiving the interventions, and completing the outcome measures ,via qualitative telephone/video conference interviews
- 5. Determine whether a social norm approach to promoting responsible gambling is acceptable to gamblers, as measured by uptake of and adherence to the intervention and feedback from qualitative interviews
- 6. Collect data on the variability of outcome measures to inform a sample size calculation for a larger trial and obtain preliminary estimates of effect size
- 7. Provide preliminary information about levels of gambling at which the intervention is most beneficial
- 8. Pilot questions relating to primary healthcare use and productivity for a future within-trial economic evaluation

Previous study hypothesis:

- 1. Assess the acceptability and feasibility of key aspects of study design, randomisation and recruitment processes
- 2. Estimate recruitment and retention rates
- 3. Assess the suitability of the outcome measures and inform the selection of the primary outcome for a future full-scale RCT
- 4. Explore participants' experiences (including barriers and facilitators) of participating in the study, receiving the interventions and completing the outcome measures, via telephone interviews
- 5. Determine whether a data-driven social norm approach to promoting responsible gambling is acceptable to gamblers, as measured by uptake of and adherence to the intervention and feedback from qualitative interviews
- 6. Collect data on the variability of outcome measures to inform a sample size calculation for a larger trial and obtain preliminary estimates of effect size
- 7. Provide preliminary information about levels of gambling at which the intervention is most beneficial
- 8. Pilot questions relating to primary healthcare use and productivity for a future within-trial economic evaluation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/09/2020, Faculty of Science and Technology Ethics Committee, Bournemouth University (Talbot Campus, Fern Barrow, Poole, Dorset, BH12 5BB; +44 (0)1202 961073; researchgovernance@bournemouth.ac.uk), ref: 33247

Study design

Online interventional randomized controlled feasibility trial with nested qualitative study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Low to moderate gambling

Interventions

Current intervention as of 25/02/2022:

Randomisation will be performed via Sealed Envelope[™], a centralised, independent, computer-based randomisation service. Participants will be allocated to one of the 4 trial arms using restricted randomisation, with random permuted blocks, in an allocation ratio of 1:1:1:1 with stratification by gender (male/female/prefer not to say or other). Participants will be randomly assigned to one of the following four arms and all interventions will be delivered for a period of 6 weeks:

- 1. Goal setting. Participants will be given the opportunity to set one SMART goal (money-related) per week around their gambling activity. Each week participants will be asked to share data about their gambling activity with the researchers, given feedback based on whether or not their goal was met and invited to set a further goal, which could be the same as the previous goal or different.
- 2. Descriptive norm. Participants will be sent messages that challenge any misperceptions they have around how much similar others gamble. This information will be presented textually, with each message focusing on a different dimension of gambling behaviour.
- 3. Injunctive norm. Participants will be sent messages that challenge any misperceptions they have around how much others believe it is appropriate to gamble. This information will be presented textually, with each message focussing on a different dimension of gambling behaviour.
- 4. Wait-list control. Participants in this arm will not receive any intervention during the study. They will be given the option to receive their choice of one of the three interventions (goal setting/descriptive norm/injunctive norm) following debriefing.

Nested qualitative study

Approximately 10-12 qualitative telephone/video conference interviews per arm will be undertaken after the intervention. Participants will be purposively sampled for diversity of

demographic characteristics. Interviews will elicit participants' experiences of the interventions and of taking part in the study. We will interview 6 participants from the wait-list control group at the end of the study.

Previous intervention:

Randomisation will be undertaken via REDCap's randomisation module with randomisation sequences generated by and uploaded from the Robust Randomisation app by an independent data manager. Participants will be allocated to one of the 4 trial arms using restricted randomisation, with random permuted blocks, in an allocation ratio of 1:1:1:1 with stratification by gender (male/female/prefer not to say or other). Participants will be randomly assigned to one of the following four arms (3 intervention, 1 wait-list control) and all interventions will be delivered for a period of 6 weeks:

- 1. Goal setting. Participants will be provided visual data about their gambling activity and given the opportunity to set one SMART goal (money-related) per week around their gambling activity. Each week participants will be given feedback based on whether or not their goal was met and invited to set a further goal, which could be the same as the previous goal or different.

 2. Descriptive norm. Participants will be sent messages that challenge any misperceptions they have around how much similar others gamble. This information will be presented both textually and graphically, with each message focussing on a different dimension of gambling behaviour

 3. Injunctive norm. Participants will be sent messages that challenge any misperceptions they have around how much others believe it is appropriate to gamble. This information will be presented both textually and graphically, with each message focussing on a different dimension of gambling behaviour
- 4. Wait-list control. Participants in this arm will not receive any intervention during the study. They will be given the option to receive visual feedback on their data following debriefing, combined with either goal setting or social normative feedback.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measure as of 17/01/2023:

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.

- 1. Proportion of participants completing the interventions, number of sessions completed, (based on whether participants have read social norm messages, or in the case of the goal-setting arm, set a goal) number of early drop-outs from the intervention
- 2. Participants' willingness to share their gambling data with researchers (goal-setting arm only) (proportion who provide their weekly data during the intervention)
- 3. Number of participants completing the screening questionnaire
- 4. Proportion of participants found eligible for the study
- 5. Proportion of participants that consent to the study out of those found to be eligible
- 6. Proportion of participants completing the study out of those registered, number of withdrawals from follow-up data collection, reasons for withdrawal between baseline and 6 months
- 7. Number of losses to follow-up and characteristics of participants lost to follow-up
- 8. Proportion of participants with complete self-reported outcome data at 6 weeks, 3 months and 6 months
- 9. Outcome measure and item completion rates at baseline, 6 weeks, 3, and 6 months

10. Feedback from qualitative interviews on the acceptability of questionnaires at baseline, 6 weeks, 3, and 6 months

Previous primary outcome measure:

Feasibility of a future full-scale randomised controlled trial (RCT) and to inform the selection of a primary outcome for a future full-scale RCT

Secondary outcome measures

Current secondary outcome measures as of 17/01/2023:

Self-reported outcomes:

- 1. Problem gambling severity measured using the Problem Gambling Severity Index (PGSI) at prebaseline to assess eligibility, baseline, 6 weeks, 3, and 6 months
- 2. Time and number of days spent gambling over the past week at baseline, 6 weeks, 3, and 6 months
- 3. Amount of money spent gambling over the past week as assessed by data from operators (that participants have given permission to be shared with the researchers) at baseline, 6 weeks, 3, and 6 months
- 4. Gambling-related cognitions assessed using The Gambling Related Cognitions Scale (GRCS) at baseline, 6 weeks, 3, and 6 months
- 5. Depressive symptoms assessed using the Patient Health Questionnaire (PHQ-8) at baseline, 6 weeks, 3, and 6 months
- 6. Anxiety symptoms assessed using The Generalized Anxiety Disorder 7-item scale (GAD-7) at baseline, 6 weeks, 3, and 6 months
- 7. Quality of life measured using the EUROHIS-QOL at baseline, 3, and 6 months
- 8. Contacts made with GP/nurse in the past 3 months will be self-reported at baseline, 3, and 6 months
- 9. Productivity assessed using a questionnaire at baseline, 3 and 6 months
- 10. Capability wellbeing using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline, 3, and 6 months
- 11. Generic Quality of Life using the EuroQol 5-Dimension-5 Level (EQ-5D-5L) questionnaire at baseline, 3, and 6 months
- 12. Descriptive and injunctive norms, including perceived descriptive norms of gambling behaviours (such as frequency, amount) and perceived norms of injunctive gambling attitudes (such as desire to gain greater control) reported at baseline, 6 weeks, 3, and 6 months
- 13. Narcissism measured using the Narcissistic Admiration and Rivalry questionnaire (NARQ) at baseline

Previous secondary outcome measures as of 25/02/2022:

- 1. Proportion of participants completing the interventions, number of sessions completed, (based on whether participants have read social norm messages, or in the case of the goal-setting arm, set a goal) number of early drop-outs from the intervention
- 2. Participants' willingness to share their gambling data with researchers (goal-setting arm only) (proportion who provide their weekly data during the intervention)
- 3. Number of participants completing the screening questionnaire
- 4. Proportion of participants found eligible for the study

- 5. Proportion of participants that consent to the study out of those found to be eligible
- 6. Proportion of participants completing the study out of those registered, number of withdrawals from follow-up data collection, reasons for withdrawal between baseline and 6 months
- 7. Number of losses to follow-up and characteristics of participants lost to follow-up
- 8. Proportion of participants with complete self-reported outcome data at 6 weeks, 3 months and 6 months
- 9. Outcome measure and item completion rates at baseline, 6 weeks, 3, and 6 months
- 10. Feedback from qualitative interviews on the acceptability of questionnaires at baseline, 6 weeks, 3, and 6 months
- 11. Self-reported outcomes:
- 11.1. Problem gambling severity measured using the Problem Gambling Severity Index (PGSI) at pre-baseline to assess eligibility, baseline, 6 weeks, 3, and 6 months
- 11.2. Time and number of days spent gambling over the past week at baseline, 6 weeks, 3, and 6 months
- 11.3. Amount of money spent gambling over the past week as assessed by data from operators (that participants have given permission to be shared with the researchers) at baseline, 6 weeks, 3, and 6 months
- 11.4. Gambling-related cognitions assessed using The Gambling Related Cognitions Scale (GRCS) at baseline, 6 weeks, 3, and 6 months
- 11.5. Depressive symptoms assessed using the Patient Health Questionnaire (PHQ-8) at baseline, 6 weeks, 3, and 6 months
- 11.6. Anxiety symptoms assessed using The Generalized Anxiety Disorder 7-item scale (GAD-7) at baseline, 6 weeks, 3, and 6 months
- 11.7. Quality of life measured using the EUROHIS-QOL at baseline, 3, and 6 months
- 11.8. Contacts made with GP/nurse in the past 3 months will be self-reported at baseline, 3, and 6 months
- 11.9. Productivity assessed using a questionnaire at baseline, 3 and 6 months
- 11.10. Capability wellbeing using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline, 3, and 6 months
- 11.11. Generic Quality of Life using the EuroQol 5-Dimension-5 Level (EQ-5D-5L) questionnaire at baseline, 3, and 6 months
- 11.12. Descriptive and injunctive norms, including perceived descriptive norms of gambling behaviours (such as frequency, amount) and perceived norms of injunctive gambling attitudes (such as desire to gain greater control) reported at baseline, 6 weeks, 3, and 6 months
- 11.13. Narcissism measured using the Narcissistic Admiration and Rivalry questionnaire (NARQ) at baseline

Previous secondary outcome measures:

- 1. Proportion of participants completing the intervention, completing the required number of sessions, number of early drop-outs from the intervention, reasons for dropouts, overall and by group, between baseline and 6 months
- 2. Participants' willingness to share their gambling data with researchers assessed by noting whether the participants share their gambling data with the researchers on request at baseline, 6 weeks, 3, and 6 months
- 3. Number of participants completing the screening questionnaire
- 4. Numbers of participants recruited from each operator
- 5. Proportion of participants found eligible for the study
- 6. Proportion of participants that consent to the study out of those found to be eligible

- 7. Proportion of participants completing the study out of those registered, number of withdrawals from follow-up data collection, reasons for withdrawal between baseline and 6 months
- 8. Number of losses to follow-up and characteristics of participants lost to follow-up between baseline and 6 months
- 9. Proportion of participants with follow-up self-reported outcome data at 6 weeks, 3, and 6 months
- 10. Overall and item completion rates at baseline, 6 weeks, 3, and 6 months
- 11. Feedback from qualitative interviews on the acceptability of questionnaires at baseline, 6 weeks, 3, and 6 months
- 12. Self-reported outcomes:
- 12.1. Problem gambling severity measured using the Problem Gambling Severity Index (PGSI) at pre-baseline to assess eligibility, baseline, 6 weeks, 3, and 6 months
- 12.2. Time and number of days spent gambling over the past week at baseline, 6 weeks, 3, and 6 months
- 12.3. Amount of money spent gambling over the past week as assessed by data from operator websites that participants share with the researchers at baseline, 6 weeks, 3, and 6 months
- 12.4. Gambling-related cognitions assessed using The Gambling Related Cognitions Scale (GRCS) at baseline, 6 weeks, 3, and 6 months
- 12.5. Depressive symptoms assessed using the Patient Health Questionnaire (PHQ-8) at baseline, 6 weeks, 3, and 6 months
- 12.6. Anxiety symptoms assessed using The Generalized Anxiety Disorder 7-item scale (GAD-7) at baseline, 6 weeks, 3, and 6 months
- 12.7. Quality of life measured using the EUROHIS-QOL at baseline, 3, and 6 months
- 12.8. Contacts made with GP/nurse in the past 3 months will be self-reported at baseline, 3, and 6 months
- 12.9. Work productivity assessed using a questionnaire about work productivity at baseline, 3, 6 months
- 12.9. Capability wellbeing using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline, 3, and 6 months
- 12.10. Health economic evaluation using the EuroQol 5-Dimension-5 Level (EQ-5D-5L) questionnaire at baseline, 3, and 6 months
- 12.11. Descriptive and injunctive norms, including perceived descriptive norm of gambling behaviours (such as frequency, amount) and perceived norms of injunctive gambling attitudes (such as desire to gain greater control) reported at baseline, 6 weeks, 3, and 6 months
- 12.12. Narcissism measured using the Narcissistic Admiration and Rivalry questionnaire (NARQ) at baseline

Overall study start date

01/06/2020

Completion date

16/02/2023

Eligibility

Key inclusion criteria

- 1. Aged ≥18 years
- 2. Resident in the UK
- 3. Gamble online a minimum of once a week or place more than 5 bets per week
- 4. Have access to the internet

- 5. Sufficient English language ability to engage with the study
- 6. Owns a smartphone

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

140 (35 per arm)

Total final enrolment

168

Key exclusion criteria

- 1. Inability to provide informed consent
- 2. Score on the Problem Gambling Severity Index (PGSI) is indicative of problem gambling

Date of first enrolment

01/12/2020

Date of final enrolment

30/06/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Bournemouth University

Department of Psychology
Faculty of Science and Technology
Talbot Campus
Fern Barrrow
Poole
United Kingdom
BH12 5BB

Sponsor information

Organisation

Bournemouth University

Sponsor details

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Sponsor type

University/education

Website

https://www1.bournemouth.ac.uk/

ROR

https://ror.org/05wwcw481

Funder(s)

Funder type

Charity

Funder Name

GambleAware

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The results will be disseminated in a peer-reviewed scientific journal, a report for funder, and a conference presentation. The results will inform the design of a definitive randomised controlled trial.

Intention to publish date

30/09/2025

Individual participant data (IPD) sharing plan

Anonymised data will be stored on Bournemouth University's data repository, BORDAR (https://bordar.bournemouth.ac.uk) which is publicly accessible.

Added 06/01/2023:

Type of data stored: quantitative and qualitative All participants gave consent to their data being stored in the data repository

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>		14/03/2023	15/03/2023	Yes	No