

# A randomized controlled trial of an Internet-based psychological treatment for disordered gambling

<b>Submission date</b> 24/04/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2019	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/01/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Gambling addiction is a common problem with serious consequences for those affected. It often leads to problems financially, in close relationships, and with mental health. At the same time, it is rare that those affected seek treatment. It is therefore important to find effective treatments that are also acceptable to most people. The aim of this study is to test Cognitive Behavioural Therapy (CBT) given over the internet, in the treatment of gambling addiction.

### Who can participate?

Adults between ages 18-75 years treated at a centre for gambling addiction in Sweden

### What does the study involve?

Participants are randomly allocated to CBT or a control treatment. Both treatments are given over the internet, with telephone support from a therapist and last for 8 weeks, but the content of the treatments differs. Gambling-related behaviour is measured at the start of the study, during treatment, at treatment end and at follow-ups at 6, 12 and 24 months after treatment.

### What are the possible benefits and risks of participating?

The main benefit is that participants will receive treatment over the internet (if they don't enter the study they will receive group therapy at the clinic) which makes it possible to partake in treatment over geographical distances and at times chosen by the participant. Possible risks are that the control treatment might be less effective, and therefore that participants allocated to the control group won't get the same treatment effect. If not satisfied with the treatment, participants will however be able to receive regular treatment at the clinic after they finish the treatment in the study.

### Where is the study run from?

Sahlgrenska University Hospital (unit for gambling addiction and screen health), Gothenburg, Sweden

When is the study starting and how long is it expected to run for?  
May 2019 to January 2025

Who is funding the study?

1. Sahlgrenska University Hospital
2. Fredrik och Ingrid Thuring's stiftelse
3. Svenska Spel's independent research council

Who is the main contact?

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## Contact information

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## Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

IKBT 631-18

# Study information

## Scientific Title

Effectiveness of an internet-based cognitive behavioural treatment for disordered gamblers in a specialized outpatient setting: a randomised controlled trial

## Study objectives

Current study hypothesis as of 07/12/2022:

This study aims to assess whether an 8-week CBT-based treatment delivered over the internet can be effective for pathological gamblers (n=64) in a clinical setting compared to a control treatment.

Main hypothesis: Participants receiving the internet CBT treatment will display significant reductions in behaviours associated with disordered gambling compared to participants in the control condition.

Secondary hypothesis 1: Participants with comorbid psychiatric symptoms will be compared with participants without after receiving the internet CBT treatment. The researchers hypothesize that both participants with and without co-morbid psychiatric symptoms (such as ADHD, depression) will benefit from the CBT treatment.

Secondary hypothesis 2: Participants receiving the internet CBT treatment will display significant reductions in irrational gambling-related beliefs compared to participants in the control condition.

Secondary hypothesis 3: Participants receiving the internet CBT treatment will display significant reductions in depressive and anxiety symptoms, and a significant increase in quality of life compared to participants in the control condition.

Previous study hypothesis:

This study aims to assess whether an 8-week CBT-based treatment delivered over the internet can be effective for pathological gamblers (n=84) in a clinical setting compared to a control treatment.

Main hypothesis: Participants receiving the internet CBT treatment will display significant reductions in behaviours associated with disordered gambling compared to participants in the control condition.

Secondary hypothesis 1: Participants with comorbid psychiatric symptoms will be compared with participants without after receiving the internet CBT treatment. The researchers hypothesize that both participants with and without co-morbid psychiatric symptoms (such as ADHD, depression) will benefit from the CBT treatment.

Secondary hypothesis 2: Participants receiving the internet CBT treatment will display significant reductions in irrational gambling-related beliefs compared to participants in the control condition.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 26/11/2018, Ethical Review Agency (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; Tel: +46 (0)10 475 08 00; Email: [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: 631-18

**Study design**

Single-center single-blinded interventional randomized control trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See study outputs table

**Health condition(s) or problem(s) studied**

Gambling disorder

**Interventions**

Participants will be randomized to either the treatment being evaluated (ICBT) or an active control group (IMI).

A randomization sequence was made before enrollment of patients by a statistician not affiliated with the study. As participants will be enrolled continually over 3 years, a procedure has been developed where the randomized sequence has been put in envelopes. As each patient is enrolled they will be randomized to one of the study arms by opening the next envelope in the sequence. In this way randomization is kept apart from the research group.

The ICBT treatment consists of an 8-week internet-delivered treatment based on cognitive behavioural therapy. Patients will work through modules containing psychoeducation and cbt-exercises, one module/week. They will have active therapist support, by short e-mail messages and short telephone contacts once a week.

The IMI is an Motivational Interviewing (MI) based active control treatment designed specifically for this study. The control treatment is made to in form be similar to the evaluated treatment, but to not contain CBT elements. It is designed to provide psychoeducation, motivational enhancement and support. It also consists of 8 modules over 8 weeks. It will contain feedback via e-mail, and telephone support. However, the content of the modules is more limited. It mainly contains psychoeducation about gambling and gambling disorder and open-ended questions congruent with MI. MI will be used for the telephone support.

## **Intervention Type**

Behavioural

### **Primary outcome measure**

Current primary outcome measure as of 07/12/2022:

Gambling-related behaviour measured using the NODS: The NORC Diagnostic Screen for Gambling Problems (NODS) (Wickwire et al., 2008). NODS will be adapted to a 14-day version. It will be administered at assessment, baseline, every 14 days of treatment, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment.

Previous primary outcome measure:

Gambling-related behaviour measured using the NODS: The NORC Diagnostic Screen for Gambling Problems (NODS) (Wickwire et al., 2008) and The Time Line Follow Back (TLFB), adapted to measure pathological gambling (G-TLFB) (Hodgins & Makarchuk 2003). NODS will be adapted to a 14-day version. It will be administered at assessment, baseline, every 14 days of treatment, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment. The GTLFB will be administered at baseline, every 7 days during treatment, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment.

### **Secondary outcome measures**

Current secondary outcome measure as of 07/12/2022:

1. Gambling-related behaviour measured using the Time Line Follow Back (TLFB), adapted to measure pathological gambling (G-TLFB) (Hodgins & Makarchuk 2003) The GTLFB will be administered at baseline, every 7 days during treatment, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment.
2. Gambling-related cognitions assessed using The Gamblers Belief Questionnaire (GBQ) (Steenbergh, Meyers, May & Whelan, 2002) at baseline, after 28 days, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment.
3. Depressive symptoms assessed using The Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001) at baseline, every 7 days during treatment, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment.
4. Anxiety symptoms assessed using The Generalized Anxiety Disorder 7-item scale (GAD-7) (Spitzer, Kroenke, Williams, & Löwe, 2006) at baseline, after 28 days, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment.
5. Quality of life assessed using The Brunnsvikien Brief Quality of Life Scale (BBQ) (Lindner et al., 2016) at baseline, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment.

Previous secondary outcome measure:

1. Gambling-related cognitions assessed using The Gamblers Belief Questionnaire (GBQ) (Steenbergh, Meyers, May & Whelan, 2002) at baseline, after 28 days, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment.
2. Depressive symptoms assessed using The Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001) at baseline, every 7 days during treatment, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment.
3. Anxiety symptoms assessed using The Generalized Anxiety Disorder 7-item scale (GAD-7) (Spitzer, Kroenke, Williams, & Löwe, 2006) at baseline, after 28 days, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment.
4. Quality of life assessed using The Brunnsvikien Brief Quality of Life Scale (BBQ) (Lindner et al., 2016) at baseline, at treatment end and at follow-ups at 6, 12 and 24 months post-treatment.

### **Overall study start date**

30/06/2018

**Completion date**

31/01/2025

## **Eligibility**

**Key inclusion criteria**

Eligible participants are all patients that are treated at the Unit for gambling addiction and screen health, Sahlgrenska University, Gothenburg, Sweden, and that meet the following inclusion criteria:

1. 18-75 years old
2. Any gender
3. Meet DSM-5 criteria for Gambling Disorder
4. Have access to the internet
5. Are able to read and write Swedish fluently

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

75 Years

**Sex**

Both

**Target number of participants**

Recruitment will continue until 64 patients have been randomised and started the treatment. With 10% pre-treatment drop-out, we expect that a total of 72 randomised patients (36 per group) are needed

**Total final enrolment**

71

**Key exclusion criteria**

Participants will be excluded if they:

1. Have somatic or psychiatric conditions that contraindicate treatment or severely hinders treatment participation (e.g. ongoing psychotic, manic or hypomanic episode, or a developmental disorder causing severe disability)
2. Have an increased risk of suicide (based on assessment during the diagnostic interview)
3. Are currently in another ongoing psychological treatment with similar content as the one offered in this study

4. Have started medication for a psychiatric condition during the last three weeks
5. Plan to start another treatment (psychotherapy or medication) for their gambling disorder during the course of the 8-week treatment

**Date of first enrolment**

08/05/2019

**Date of final enrolment**

30/11/2022

## Locations

**Countries of recruitment**

Sweden

**Study participating centre**

**Sahlgrenska University Hospital (unit for gambling addiction and screen health)**

Sahlgrenska Universitetssjukhuset

Gothenburg

Sweden

41345

## Sponsor information

**Organisation**

Sahlgrenska University Hospital

**Sponsor details**

Addiction Clinic

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/04vgqjj36>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Sahlgrenska University Hospital

## Funder Name

Fredrik och Ingrid Thuring's Stiftelse

## Alternative Name(s)

Fredrik and Ingrid Thuring's Foundation

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

Sweden

## Funder Name

Svenska Spel's independent research council

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Added 21/01/2025:

Results have been published in 2023 (<https://doi.org/10.3389/fpsy.2023.1243826>). The results of follow-up data will be published on approximately 30/06/2026.

## Intention to publish date

30/06/2026

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. The anonymized encrypted data will be stored on local servers as per the standard procedures of Sahlgrenska University Hospital.



## IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 1.0		28/06/2022	No	Yes
<a href="#">Statistical Analysis Plan</a>		25/11/2022	07/12/2022	No	No
<a href="#">Results article</a>		11/12/2023	27/12/2023	Yes	No