

Web-based cognitive behavioural self-help therapy to reduce cocaine consumption in problematic cocaine users: Randomised controlled trial

TITLE

1a-i) Identify the mode of delivery in the title

Yes.

Title: "Web-based cognitive behavioural self-help therapy to reduce cocaine consumption in problematic cocaine users: Randomised controlled trial"

1a-ii) Non-web-based components or important co-interventions in title

not applicable

1a-iii) Primary condition or target group in the title

Yes.

Title: "Web-based cognitive behavioural self-help therapy to reduce cocaine consumption in problematic cocaine users: Randomised controlled trial"

ABSTRACT

1b-i) Key features/functionality/components of the intervention and comparator in the METHODS section of the ABSTRACT

Yes

Methods section from the abstract "Interactive cognitive-behavioural modules and a consumption diary for the reduction of cocaine use were implemented and compared with a psycho-educative control condition in a randomised controlled 6-week study."

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Yes

Objective from the abstract: "To test the feasibility and effectiveness of anonymous, fully automated web-based self-help therapy as an alternative to outpatient treatment services for cocaine users."

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

Yes

Methods section from the abstract "Participants for the web-based trial were recruited by various online and offline media."

1b-iv) RESULTS section in abstract must contain use data

Yes

Methods section from the abstract: "The frequency and quantity of cocaine use entered into the consumption diary and the Severity of Cocaine Dependence Scale (SDSc) were assessed as the main outcomes among 196 cocaine-using participants of the intervention group and 100 participants of the control group."

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

Yes

Results section from the abstract: "The low number of participants who completed the SDSc and the CCQ-B limited the explanatory power of the variables assessed by these questionnaires."

INTRODUCTION

2a-i) Problem and the type of system/solution

Yes

Introduction: "Older and higher-educated cocaine users, who are likely to be better integrated into society, are rarely reached by standard treatment. Presumably, the majority of these individuals consume cocaine on a quasi-controlled basis, and only a small fraction of them is likely to take advantage of treatment [4]. However, some of these users are expected to switch from controlled use to problematic use [5]. For higher-educated and integrated cocaine users, anonymous interventions that follow the principle of concurrent cover (i.e., non-invasive, low-cost interventions in which therapeutic intensity can be enhanced according to need and extended to face-to-face treatment) appear to be more appropriate. Thus, a diversification of the available outpatient treatment services for cocaine users in this direction is favourable."

2a-ii) Scientific background, rationale: What is known about the (type of) system

Yes: Introduction

Web-based self-help programs that reduce problematic consumption are able to reach "hidden" consumer groups in the general population due to their low treatment threshold and non-restrictive setting for intervention [6]. Furthermore, these programs show a remarkably positive cost-benefit relation [7], which is of interest in industrialised countries with exorbitant health costs but widespread Internet access. These programs have been tested primarily in on individuals with tobacco dependence [8], or problematic alcohol use. The existing reviews and meta analyses on web-based interventions for tobacco smoking and alcohol use showed that these interventions are superior to no or minimal interventions. However, their effect sizes are predominantly small. Evidence concerning their effectiveness compared to face-to-face interventions is inconclusive. To date, only few studies exist which tested the effectiveness of web-based interventions for the treatment of illegal substance use. Within a controlled trial, a web-based intervention to help young people to quit or reduce their cannabis use was tested [9,10] Despite some methodological constraints, the results of this study showed that the web-based intervention is promising in order to reduce cannabis consumption compared to no intervention. To date, no trial testing the acceptance and efficacy of a web-based program for the treatment of problematic cocaine use has been conducted.

METHODS

3a) CONSORT

Yes

Introduction

"We expected that the participants in the Snow Control therapy group would show greater reductions in cocaine consumption at the 6-week termination of treatment than the control participants. Moreover, we assumed that the participants in the therapy group would improve more significantly with respect to the secondary outcomes of cocaine craving, reduction of alcohol and illicit substance use other than cocaine, and depression characteristics between the baseline and 6-week treatment termination. We also expected the participants in the therapy group to show significantly greater retention."

3b-i) Bug fixes, Downtimes, Content Changes

There were no changes made on the intervention during the trial or due to other unexpected events.

4a-i) Computer / Internet literacy

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Yes

Methods: Recruitment

"The study population was recruited through the Snow Control website, several websites of local outpatient treatment centres in the Canton of Zurich and national nightlife prevention organisations, and tailored advertisements on national social media platforms in the second half of 2010 and in 2011. In addition, advertisements were placed in national Internet forums, 2 newspapers and 2 television reports on the Swiss TV."

4a-iii) Information giving during recruitment

4b-i) Report if outcomes were (self-)assessed through online questionnaires

Yes

Methods section: Measurement instruments

"All outcome measures were assessed through online questionnaires."

4b-ii) Report how institutional affiliations are displayed

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

5-ii) Describe the history/development process

5-iii) Revisions and updating

5-iv) Quality assurance methods

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

5-vi) Digital preservation

5-vii) Access

Yes

Methods: Measurement instruments

"After providing informed consent, subjects who met study entry criteria created a personal and secure login and password and received an automated e-mail notification with their access information."

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Yes

Methods: Interventions

"Snow Control is based on methods of cognitive behavioural therapy (CBT)

that have been tested on cocaine addicts [13,14], principles of

motivational interviewing [15], current self-control practices and the

established relapse-prevention model [16-18].The therapy is structured into 8 modules that are activated for week-by-week access in the first 3 weeks

and 4 additional voluntary modules that can be activated during weeks 4-6. A detailed description of the intervention can be viewed in the study protocol

[12] (trial registration ISRCTN93702927)."

See also stucy protocol published in BMC Psychiatry

5-ix) Describe use parameters

5-x) Clarify the level of human involvement

5-xi) Report any prompts/reminders used

There were weekly e-mail reminders as described in the study protocol

Snow control - an RCT protocol for a web-based self-help therapy to

reduce cocaine consumption in problematic cocaine users.

Schaub M, Sullivan R, Stark L.

BMC Psychiatry. 2011;11:153

5-xii) Describe any co-interventions (incl. training/support)

There were no co-interventions in addition to the eHealth intervention

but an emergency procedure which is described in Methods: Interventions:

"To avoid serious harm to the participants during the interventions,

safety was provided by a detailed consent procedure with thorough safety

instructions and by a continuously accessible 24-hour emergency list

(including the numbers of emergency help lines and contact information

for the study team and the webmaster), regardless of whether participants withdrew or dropped out of the study. Moreover, during the 6-

week intervention phase, participants had the opportunity to contact a corresponding outpatient clinic in a nearby city by telephone (lists were provided

with opening hours, web links, postal addresses, and telephone numbers)."

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

Yes

See also study protocol published in BMC Psychiatry: Sample size calculation

"According to the pilot study, we expect 70% of the participants to quit the study before completion at six weeks. We thus aim to recruit a total of 170 participants at baseline."

7b) CONSORT

Interim analyses were not intended

8a) CONSORT

Yes

Methods: Interventions:

"After successful registration, participants were were individually randomised (1:1) to one of two “parallel” groups allocated to the intervention or control group by an automated random computer function."

8b) CONSORT

There were no restrictions in the randomisation procedure

9) CONSORT

Methods

Interventions

"After successful registration, participants were were individually randomised (1:1) to one of two “parallel” groups allocated to the intervention or control group by an automated random computer function."

10) CONSORT

Methods

Interventions

"After successful registration, participants were were individually randomised (1:1) to one of two “parallel” groups allocated to the intervention or control group by an automated random computer function."

11a-i) Specify who was blinded, and who wasn't

Yes

Methods: Interventions:

"Participants were blinded to the interventions."

Those doing data analysis were not blinded concerning the study groups.

11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”

11b) CONSORT

not relevant

12a) CONSORT

Methods: Analyses

"Data were analysed according to the intention-to-treat principles. Stable multiple data imputations and generalised estimating equations could not be performed because we observed too many dropouts for these procedures, as previously expected and estimated in the randomised control trial design [12]. Thus, we referred to complete case analyses (participants who remained in the study from the beginning to the end of the study intervention)."

12a-i) Imputation techniques to deal with attrition / missing values

Yes

Methods: Analyses:

"Thus, we referred to complete case analyses (participants who remained in the study from the beginning to the end of the study intervention)."

12b) CONSORT

Subgroup analyses were not possible due to small sample sizes.

RESULTS

13a) CONSORT

Yes

Methods section: Figure 1 (Flow diagram)

13b) CONSORT

Yes

Methods section: Figure 1 (Flow diagram)

13b-i) Attrition diagram

14a) CONSORT

Yes

Introduction

"Snow Control, a 6-week Internet-based self-help therapy program for problematic cocaine users who intend to control, reduce or stop their consumption of cocaine, was tested in 2010 and 2011 and compared with a control condition"

14a-i) Indicate if critical "secular events" fell into the study period

14b) CONSORT

Yes

Methods: Recruitment

Recruitment ended after the intended number of subjects in the study protocol was exceeded (n=176).

15) CONSORT

Yes

Table 1 in the Results section

15-i) Report demographics associated with digital divide issues

Yes

Table 1 in the Results section

16-i) Report multiple "denominators" and provide definitions

Yes

Methods section: Figure 1 (Flow diagram)

16-ii) Primary analysis should be intent-to-treat

17a) CONSORT

Yes

See results Table 2

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

17b) CONSORT

not applicable - we did not have binary primary outcome measures

18) CONSORT

Subgroup or adjusted analyses were not conducted due to small sample sizes

18-i) Subgroup analysis of comparing only users

19) CONSORT

Yes: see Results section: Adverse events

"During the study, 13 participants contacted the outpatient treatment service for additional help, as indicated on the website. Five of these participants received medical advice by telephone, and 8 entered the outpatient treatment service because they found the help received through the website to be insufficient. Most of these participants reported impulsive cocaine use and/or severe psychiatric co-morbidity."

19-i) Include privacy breaches, technical problems

19-ii) Include qualitative feedback from participants or observations from staff/researchers

DISCUSSION

20-i) Typical limitations in ehealth trials

Yes

See discussion

"Although the number of questionnaires was limited, the subjects demonstrated a clear aversion to completing questionnaires. This aversion was the primary flaw in the study design. Many subjects filled out the consumption diary, used the designed modules or read the psycho-educative texts, but they simply closed their Internet browsers when the questionnaires began. The implementation of telephone contact to increase study retention, as performed in similar studies for the reduction of alcohol [9,10] or tobacco use [8], was clearly rejected in the pilot study [12] because cocaine users may fear repressive activities by the police or other authorities. Furthermore, the compensation (40 Euros) for the follow-up assessment did not motivate the subjects to log in again and complete the questionnaires.

The drop-out rates for the use of the consumption diary (81.2% in the intervention and 92% in the control condition) were higher than we expected (70%) when we designed the study as a randomised controlled trial. In addition to inclusion in the intervention group, factors that contributed to retaining subjects in treatment until Week 6 included low severity of cocaine dependence, age, and depression symptoms, suggesting that the online self-help format is difficult to follow for more severely cocaine-dependent subjects and has better retention for depressed and older cocaine users."

21-i) Generalizability to other populations

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

Yes

see Discussion

"The online self-help therapy increased treatment retention and helped those subjects who remained in treatment to reduce co-occurring alcohol binge drinking in the intervention group, whereas binge drinking increased in the control group. Subjects in the intervention group who remained in treatment reduced their average weekly use of cocaine in milligrams to a lower extent overall than those in the control group. The average weekly cocaine-free days were somewhat higher in the control group but did not change substantially in either group."

22-ii) Highlight unanswered new questions, suggest future research

Other information

23) CONSORT

Yes

trial registration mentioned in the abstract

" (Trial Registration: Current Controlled Trials ISRCTN93702927.)"

24) CONSORT

Yes

The trial protocol is published in BMC Psychiatry (2011) and cited in the study

Schaub, M., R. Sullivan, et al. (2011). "Snow control - an RCT protocol for a web-based self-help therapy to reduce cocaine consumption in problematic cocaine users." BMC psychiatry 11: 153.

25) CONSORT

Funding is mentioned in the section "Acknowledgements"

X26-i) Comment on ethics committee approval

x26-ii) Outline informed consent procedures

X26-iii) Safety and security procedures

X27-i) State the relation of the study team towards the system being evaluated