Optimizing and Innovating Blended Interventions and Aftercare for Alcohol Addiction (OptiBlend): A Randomized Controlled Trial

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Primary objective: In the RCT, we expect to find at least a small to medium (d>=.35) between-group effect between BL1 and BL2 compared to TAU. In the EMA, we expect to find at least a medium (d>=.6) between-group effect between the BL1/BL2 and…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57089

Source
ToetsingOnline

Brief title
OptiBlend: Optimizing and innovating blended treatment for addiction

Condition

- Other condition

Synonym
alcohol addiction, Alcohol use disorder

Health condition

alcohol use disorder, with or without other substance use disorders

Research involving

Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Alcohol Use Disorder, Blended care, Cognitive Behavioral Therapy, Internet-Based Intervention

Outcome measures

Primary outcome

The primary outcome in this study is the total alcohol consumed, based on the number of standard drinks (10 grams of ethanol) in the last 7 days.

Secondary outcome

The secondary outcomes of this study are (1) the odds of decreasing one's WHO risk drinking level by at least 1 level, and (2) treatment response. Treatment response indicates whether treatment is deemed successful or not. The treatment is deemed successful if both conditions are met (a) no more than 8 alcohol drinking days in the past 30 days prior to measurement and (b) no heavy drinking days (>3 standard drinks/day [females], >4 standard drinks/day [males]) in the past 30 days prior to measurement.

Study description

Background summary

Traditionally, therapy for alcohol use disorder with or without substance use disorder (A/SUD) therapy has been individual or group face-to-face (F2F) therapy. Although these F2F programs are evidence-based, they suffer from a number of shortcomings. Blended treatment combines the most valuable aspects of

digital and F2F treatments into one integrated protocol. Using this approach, part of F2F treatment is replaced by digital components with digital therapist feedback, while the F2F relationship between the therapist and patient is also retained. F2F contact ensures that patients benefit from a supportive therapeutic relationship, which likely increases motivation to complete treatment. Digital elements, however, provide flexibility in time, allowing patients to access treatment modules with most relevance to them in between F2F sessions where therapist feedback is provided on exercises and other input (Månsson et al., 2013). By extending access to treatment by providing online sessions, the number of required F2F sessions can potentially be reduced, which may result in cost-savings and reduced therapy waitlists. Mental healthcare institutions are increasingly using blended treatment, and an evidence base has emerged demonstrating clinical and cost-effectiveness of blended treatment for many psychiatric disorders, but A/SUD studies addressing clinical and cost-effectiveness of blended treatment are sparse and thus highly needed.

Cognitive behavioral therapy (CBT) is a protocolized treatment, in which patients have F2F sessions with a psychologist. In between the sessions, patients work on exercises in a workbook. There is a blended version of CBT, in which patients have the F2F sessions with their therapist, and work on the exercises in an online environment instead of in the workbook. In our study, the online modules were updated: new modules about sleep and nutrition were included, and the module on relapse prevention in the aftercare period was expanded. By including an extensive interactive self-guided aftercare module, the impact of the intervention can be extended in time, even with limited efforts of a therapist. Incorporating transdiagnostic lifestyle modules (e.g., nutrition, sleeping), which would normally not be sufficiently covered in a F2F A/SUD therapy program due to time constraints, likely improves the overall impact of the intervention and patients* wellbeing. This new blended treatment will be given in two forms: with 14 F2F sessions in BL1 and 8 F2F sessions in BL2. In BL2, if more F2F sessions are deemed necessary as based on the clinical view of the practitioner, 14 F2F sessions will be given as well. These two forms of blended treatment will be compared to each other and with a standard F2F CBT treatment (treatment as usual: TAU).

Study objective

Primary objective: In the RCT, we expect to find at least a small to medium (d>=. 35) between-group effect between BL1 and BL2 compared to TAU. In the EMA, we expect to find at least a medium (d>=.6) between-group effect between the BL1/BL2 and TAU patients with regard to improvement of sleep and healthy nutrition. Secondary objectives: 1. We expect to find that BL2 is non-inferior to BL1, taking into account a non-inferiority margin of 10%. 2. We expect to find that BL2 is more attractive in terms of cost-effectiveness than BL1 and TAU, also when taking into account the health sector costs perspective and the wider societal perspective (e.g., productivity costs).

Study design

A multicenter, 3-arm, single-blind randomized controlled trial (RCT) will be conducted to evaluate the effects and costs of an innovated blended treatment with (BL2) and without (BL1) intensity-personalization and F2F TAU. Assessments will take place at baseline (before randomization), and 3 months, 6 months, 12 months, and 18 months after randomization. A cost-effectiveness evaluation will be performed in line with suggestions by CHEERS 2022 guidelines and the Dutch guideline for economic evaluation, e.g., in agreement with the intention-to-treat principle, with missing data addressed using multiple imputation. The trial will be registered in the Dutch Trial Register after the METC approval. The duration of the study is planned for 3.5 years (24 months inclusion period and 3, 6, 12, 18 month follow-up).

Participants will be enrolled from four participating centers in the Netherlands. A total of 298 patients (ca. 99 per trial arm) will be included, with 90 patients (30 per trial arm) simultaneously participating in a nested ecological momentary assessment (EMA) study. Trial arm allocation will be performed in a 1:1:1 ratio using a stratification procedure to minimize inter-group imbalances in trial site. As participants are invited to the EMA study before the randomization to the RCT, equal distributions of the EMA participants over the three trial arms can be expected. Randomization will be performed digitally with Castor EDC randomization software.

Intervention

Treatment as usual (TAU, comparator intervention): TAU is a manual-based cognitive behavioural therapy and motivational interviewing (CBT/MI) intervention, consisting of up to 14 individual F2F sessions. TAU is broadly implemented in the Netherlands. Its effectiveness is supported by a number of RCTs and reviews cited in the multidisciplinary guideline on alcohol treatment (Dutra et al., 2008).

Investigational treatment, innovated blended intervention modules: Both intervention groups (BL1 and BL2) receive the blended treatment with updated versions of the TAU materials and additional add-on modules (comparable with an e-learning). The modules include process support by a psychologist during the F2F sessions. The content of the modules is based on existing internet-based (guided) self-help materials developed by Arkin/Jellinek and is based on CBT/MI and tailored to adult patients with a diagnosis of AUD and possible other SUD diagnoses. The blended intervention has a per-protocol duration of 3-4 months + aftercare module (i.e., no therapist involvement).

Investigational treatment reduced F2F intensity: The first intervention group (BL1) will receive the updated blended treatment as described above with 14 F2F sessions. The second intervention group (BL2) will receive this same treatment

with reduced F2F intensity, meaning that they receive 8 F2Fsessions when possible Instead of the F2F sessions, the patients in the BL2 treatment arm will do more of their treatment modules online, with the option of discussing the content of these modules in the more limited F2F sessions. If 8 F2F sessions are deemed too few as based on the clinical opinion of the practitioner, patients will receive 14 F2F sessions in BL2 Patients in BL2 will thus either receive the short or the long version of the blended treatment. While the long version will consist of 14 weekly face to face sessions, the short version will consist of only 8 weekly to biweekly sessions, complemented with 6 online feedback sessions by the practitioner in the online platform.

Study burden and risks

Burden associated with participating in the RCT and the nested EMA is expected to be negligible because the study is mainly conducted online in parallel to participants* F2F treatment. All participants are asked to fill out a baseline and four follow-up questionnaires, which will not take more than 45 minutes to complete. EMA participants are asked to additionally answer a brief questionnaire via a smartphone application for seven consecutive days (max. three minutes per day) at three time points during the RCT. The risk associated with participating in the study is expected to be negligible, because the participants get an evidence-based and widely used psychological treatment (cognitive behavioral treatment for addiction: TAU) or one of the updated, blended versions of this same treatment with additional content (BL1/BL2).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. AUD as primary diagnosis
2. Age 18+
3. At least moderately proficient in Dutch
4. In possession of a smartphone and a tablet or computer at home
5. Voluntarily enrolled for A/SUD treatment at one of four trial sites
6. A current regular indication for blended care by an addiction treatment professional at intake

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Acute psychosis
2. Dementia
3. Indication for inpatient A/SUD treatment
4. Indication for involuntary or forensic care

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-12-2024
Enrollment:	298
Type:	Actual

Ethics review

Approved WMO Date:	17-10-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2025
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84117.018.23