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RESEARCH PAPER

Efficacy of acceptance and commitment therapy as a stand-alone treatment for Insomnia: Protocol of a randomized waitlist controlled trial

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Abstract
While Acceptance and Commitment Therapy for Insomnia (ACT-I) has been proposed as a promising alternative to Cognitive Behavioral Therapy for Insomnia, its efficacy as a distinct alternative, without sleep restriction and stimulus control, remains largely unknown. In this protocol paper, we describe a randomized controlled trial that aims to test the efficacy of ACT-I as a stand-alone intervention for insomnia. Adults with insomnia (N = 80) will be randomly allocated to five individual sessions of ACT-I or a waitlist control group. The main objective is to assess whether ACT-I is superior to the control group in improving insomnia severity, alongside secondary outcomes including sleep diary measures, anxiety, depression, general well-being, and sleep-related quality of life. Additionally, we aim to explore potential mechanisms of ACT-I, including psychological (in)flexibility, sleep-related arousal, dysfunctional cognitions, and sleep-related safety behaviors. Both the treatment and waiting period span 7 weeks. Assessments take place at baseline (pre), after 4 weeks (mid), and after 8 weeks (post), followed by a 3- and 6-month follow-up for the ACT-I group. Treatment effects will be analyzed with mixed linear regression based on the intention-to-treat principle, and potential

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mechanisms will be explored with network intervention analysis. This study contributes to the understanding of ACT-I's treatment effects and potential working mechanisms, informing clinical practice on whether ACT-I without sleep restriction or stimulus control could provide an adequate alternative treatment for insomnia. Trial registration number: NCT06336551.

Introduction

Background

Insomnia affects 6—10% of the population and is diagnosed in case of persistent trouble initiating sleep, maintaining sleep, and/or early morning awakening, leading to significant impairments in daytime functioning (Morin & Jarrin, 2022; American Psychiatric Association, 2013). Patients with insomnia generally report lower well-being and quality of life (Kyle et al., 2010), more health-related problems (Morin & Jarrin, 2022), and higher rates of depression and anxiety (Hertenstein et al., 2023). Insomnia is considered a transdiagnostic factor in mental disorders (Van Someren, 2021) and an economic burden due to increased healthcare use and work absenteeism (Daley et al., 2009).

In most Western countries, the first-line treatment of insomnia is Cognitive Behavioral Therapy (CBT-I; Riemann et al., 2023). CBT-I shows large and clinically relevant treatment effects (van Straten et al., 2018). Still, unfortunately, about 50% of the patients who receive CBT-I do not fully remit and 25—40% show no clinical treatment response (Baron & Hooker, 2017; Edinger et al., 2021). When CBT-I is unsuccessful there is currently no evidence-based psychological treatment alternative (Riemann et al., 2023).

Acceptance and commitment therapy for insomnia (ACT-I)

Acceptance and Commitment Therapy (ACT) shows promise as an alternative treatment for insomnia. ACT is an efficacious third-wave behavioral treatment that offers an alternative to CBT for a wide variety of mental disorders (Gloster et al., 2020). ACT protocols tailored to insomnia (ACT-I) have demonstrated positive treatment effects in small-scale studies and larger ACT-I trials are now strongly encouraged (Paulos-Guarnieri et al., 2022; Riemann et al., 2023; Ruan et al., 2022).

ACT-I mainly focuses on breaking the vicious circle of trying to control sleep (Lundh, 2005). Patients with insomnia often develop various strategies and rules to control sleep, which may inhibit the automatic expression of sleep and subsequently worsen insomnia (Espie et al., 2006). ACT-I introduces mindfulness techniques to let go of such control and respond more effectively to distressing sleep-related thoughts and feelings (Ong et al., 2012). Unlike solely mindfulness-focused protocols for insomnia, ACT-I also includes committed action, which involves making behavioral changes driven by personal values. Patients are stimulated to engage in meaningful daytime activities, even in the presence of symptoms (Miller-Mendes et al., 2023).

The conceptual model underlying ACT-I centers on psychological (in)flexibility (Hayes et al., 2011). Psychological *in*flexibility is viewed as a key cause of distress and refers to avoiding and judging inner experiences, getting absorbed in unwanted thoughts or feelings, lacking awareness, lacking contact with personal values, and responding to challenging experiences with inactivity, impulsivity, or rigidity (Hayes et al., 2011). The opposite, psychological flexibility, consists of six skills that are seen as key to well-being: being open to experience, unhooking from distressing thoughts or rigid rules, being present, noticing inner experiences, and responding flexibly and in line with personal values (Hayes et al., 2011).

Psychological flexibility is hypothesized to break the influence of perpetuating factors of insomnia (Rash et al., 2022), such as arousal (Riemann et al., 2010), safety behaviors (Harvey, 2002b), and dysfunctional cognitions around sleep (Harvey, 2002a). These are theory-based assumptions; the empirical study of ACT-I's working mechanisms is yet to begin. Table 1 summarizes the theorized meaning of the six psychological flexibility skills in the context of ACT-I and insomnia's perpetuating factors (Miller-Mendes et al., 2023; Harris, 2019).

The strongest evidence for ACT-I comes from studies that have combined ACT-I with behavioral elements of CBT-I, such as sleep restriction or stimulus control (Paulos-Guarnieri et al., 2022). These studies have generally found improvements in insomnia, quality of life, and symptoms of depression and anxiety, in the range of effects observed in CBT-I (Chapoutot et al., 2021; El Rafihi-Ferreira et al., 2021; Hertenstein et al., 2024; Martin et al., 2023). However, given that sleep restriction and stimulus control are generally considered the most effective elements of CBT-I (Maurer et al., 2021), these studies remain inconclusive as to the stand-alone impact of ACT-I. An effective stand-alone ACT-I protocol is of specific clinical interest, as it would offer a distinct alternative for patients who do not prefer or respond well to sleep restriction or stimulus control (Kyle et al., 2011; Vincent & Lionberg, 2001). Notably, prior studies have shown that insomnia therapies that omit such behavioral elements, such as mindfulness-based therapy or cognitive therapy for insomnia, can also lead to insomnia improvements (Harvey et al., 2014; Wang et al., 2020).

So far, only a few studies have tested stand-alone ACT-I. Three small Randomized Controlled Trials (RCTs; $N = 30—40$) observed improvements in insomnia severity, sleep quality, depression, and anxiety (Rafihi-ferreira et al., 2023; Shin et al., 2023; Zakiei et al., 2021), with inferior insomnia remission rates compared to CBT-I (Rafihi-ferreira et al., 2023). Improvements in sleep outcomes, depression, anxiety, as well as psychological flexibility were found in one

Table 1 Psychological Flexibility Skills in the Context of ACT-I.

ACT skill	Theorized meaning in ACT-I
Self-as-context	Using the observing part of the self to notice inner experiences, such as sleep-related thoughts, feelings, and sensations of arousal, instead of identifying with them.
Acceptance	Increasing the willingness to experience unpleasant sleep-related feelings, such as arousal or daytime fatigue, as an alternative to trying to avoid, control, or change these inner experiences.
Defusion	Using techniques to unhook and reduce the grip of distressing thoughts or unhelpful sleep-related cognitions, as an alternative to worrying or ruminating. Rather than rationality, thoughts are judged on '*workability*': Is getting caught up in this thought helpful at this moment? This offers aid even when thoughts may hold some truth, such as distressing thoughts about health risks related to insomnia.
Values	Realizing what matters most in life and focusing on areas and activities that provide meaning and quality of life, instead of prioritizing sleep or staying absorbed in solving the sleep problem.
Committed action	Making '*towards moves*': effective actions that align with values and help create a better life. Incorporating sleep hygiene with a friendly intention to take care and welcome sleep, rather than to control sleep. Engaging in valued activities even when daytime symptoms of insomnia are present.
Present moment awareness	Flexibility in directing attention, reducing sleep-related attentional bias and automatic sleep safety behavior by being present with what is happening in the here and now.

larger RCT (N = 140), but with a highly specific population (i.e., adults with insomnia following acute cerebral infarction; Wang et al., 2022). Another large RCT (N = 299) found no sleep improvements, but its ACT protocol was primarily focused on chronic pain rather than insomnia (Wiklund et al., 2018). Importantly, a recent RCT amongst adults with insomnia (N = 227) found that stand-alone ACT-I significantly reduced insomnia severity at post-treatment (d = 1.4) and 6-month follow-up (d = 1.5). These reductions were superior compared to a waitlist condition (d = .6) but inferior compared to CBT-I (d = .2; El Rafihi-Ferreira et al., 2024). Taken together, the evidence for the efficacy of stand-alone ACT-I remains limited, and more sufficiently powered RCTs are needed to establish stand-alone ACT-I as an evidence-based treatment alternative for insomnia. Studying stand-alone ACT-I also provides an opportunity to explore the mechanisms through which ACT-I may achieve its treatment effects.

Trial objectives

This protocol paper describes an RCT of the efficacy of ACT-I as a stand-alone treatment for insomnia compared to a waitlist (WL) control group. The main objective is to determine whether, in line with our hypotheses, ACT-I is superior to WL in improving insomnia severity (primary outcome), alongside sleep diary outcomes, depression, anxiety, general well-being, and sleep-related quality of life (secondary outcomes). The second objective is to explore potential working mechanisms of ACT-I. For this, we will measure psychological (in)flexibility, sleep-related arousal, dysfunctional cognitions, and sleep-related safety behaviors, to see how these processes develop and interrelate following ACT-I.

Method

Design

In this single-center RCT adults with insomnia (N = 80) will be randomly assigned to five individual sessions of ACT-I or a WL group. WL is chosen as an ethical passive comparator. In both groups, participants will complete assessments of outcomes before (week 0), during (week 4), and after (week 8) treatment or the 7-week waiting period. The ACT-I group will repeat these measures at a 3-month (week 21) and 6-month (week 34) follow-up. Fig. 1 shows the proposed study flow. This protocol follows the SPIRIT 2013 guidelines (Chan et al., 2013; see Appendix A).

Participants

Participants are eligible if they meet all of the following criteria: (1) insomnia severity index (ISI) score above the clinical cut-off for moderate to severe insomnia (ISI $\geq$ 15, Morin et al., 2011), (2) clinical insomnia disorder diagnosis as confirmed by the SCID-S-5 insomnia interview (First et al., 2015/2018), (3) age of 18 years or above, (4) proficiency in Dutch, and (5) ability to come to the treatment site. Participants are excluded when they: (1) have previously received ACT, (2) have started psychotherapy within the last 6 months or are currently awaiting psychotherapy, (3) have changed their psychoactive medication in the last 3 months, (4) report having a diagnosis of psychosis or schizophrenia, or (5) report severe depressive complaints or active suicidal ideation (severity based on BDI-II total $\geq$ 29, suicidal ideation based on BDI-II item nine score two or three, respectively; Beck et al., 1996).

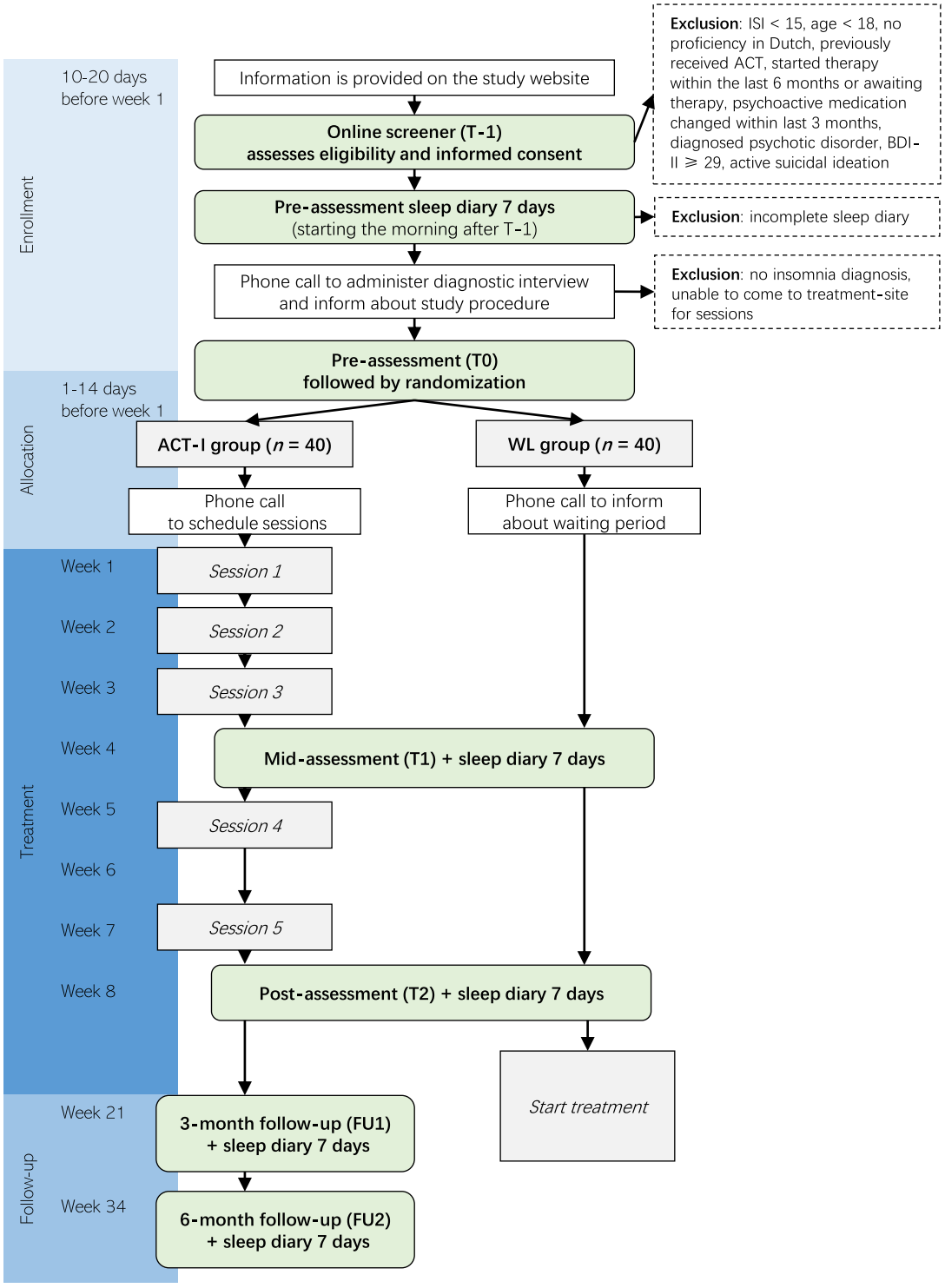

Fig. 1 Study Flow Diagram.

Sample size

We aim to include 80 participants, which would yield 80% power to detect a small effect size (d = .32) based on sensitivity power calculations using G*Power 3.1 (α = .05, r among repeated measures = .5, and non-sphericity correction = 1; Faul et al., 2007). To be conservative with a-priori estimates, we based the power analysis on a between-within interaction in mixed ANOVA instead of a linear mixed model, as both are members of the same general linear mixed model family (Liu et al., 2012).

Randomization

Random treatment allocation is programmed within Qualtrics (Qualtrics, Provo, UT) using a 1:1 allocation ratio. As

enrollment takes place over several months, we use blocked randomization to produce balanced groups (Everitt & Wessely, 2008). To minimize predictability, the block sizes vary randomly between two, four, and six.

Blinding

Diagnostic interviews and pre-assessment (T0) are blinded, as allocation takes place after the pre-assessment has been completed. After randomization, therapists and participants are aware of the allocated treatment, as well as researchers and assistants contacting participants. Observer bias is somewhat diminished by having all assessments completed online in private. To ensure blinding during data analysis, identifiers such as condition and participant number are randomly re-coded by an independent researcher.

Procedure

Participants are recruited through social media advertisements (e.g., Instagram and Facebook) and directed to the study website (https://www.insomnie.nl) for information and screening. All assessments are conducted online via Qualtrics (see Table 2 for an overview of assessments). The screener (T-1) checks eligibility and includes informed consent, after which eligible participants complete a sleep diary for 7 days and receive a telephone interview to assess the presence of an Insomnia Disorder.

Upon finishing the sleep diary, participants receive an automated email invitation to complete the pre-assessment (T0, week 0). At the end of the pre-assessment, participants are automatically randomized to either ACT-I or WL and informed about their group. After allocation, participants are called to schedule the first treatment as soon as possible (ACT-I) or after the waiting period (WL).

Participants complete the mid-assessment after session three (T1, week 4), and the post-assessment after session five (T2, week 8). We selected this mid-assessment point to provide information about the unique effect of mindfulness-based techniques, as the first three sessions focus mainly on acceptance, defusion, and observing skills, while the last two sessions focus more on values (see Table 3). After 3 and 6 months, the ACT-I group receives email invitations for follow-up assessments (FU1 and FU2). Every assessment moment is followed by a 7-day sleep diary. Participants who do not complete follow-up assessments receive up to three reminder emails and a phone call. The WL group receives ACT-I treatment after completing T2, without further assessments.

Treatment takes place at the therapy facility of the clinical psychology program group of the University of Amsterdam (UvA; Psypoli). There is no financial compensation for participation. Participants are informed that they can withdraw from the study at any time. In case of drop-out of treatment, participants are encouraged to continue the assessments, if possible. Throughout the study, participants can contact the researchers via email for questions and concerns. The study was approved by the internal Ethical

Table 2 Summary of Measures at Different Assessment Moments.

Measure	Description	T-1	T0	T1	T2	FU1	FU2
Primary outcome							
ISI	Insomnia severity	+	+	+	+	+	+
Secondary outcomes							
Sleep diary	Sleep diary measures	+		+	+	+	+
HADS-A	Anxiety symptoms		+	+	+	+	+
PHQ-9	Depression symptoms		+	+	+	+	+
MHC-SF	General well-being		+	+	+	+	+
GSII	Sleep-related quality of life		+	+	+	+	+
MPFI-24	Psychological (in)flexibility		+	+	+	+	+
PSAS	Pre-sleep arousal		+	+	+	+	+
SRBQ-20	Sleep safety behavior		+	+	+	+	+
DBAS-16	Dysfunctional sleep cognitions		+	+	+	+	+
Other measures							
Demographics		+					
BDI-II	Depression severity	+					
SCID-5-S Insomnia	DSM-5 Insomnia Disorder	+					
Homework practice				+	+		
Medication use		+			+	+	+
Treatment satisfaction					+		
Concomitant care					+	+	+
Adverse events					+	+	+

Note. T-1 = Enrollment, T0 = Pre-treatment assessment, T1 = Mid-treatment assessment, T2 = Post-treatment assessment, FU1 = 3-month follow-up, FU2 = 6-month follow-up. ISI = Insomnia Severity Index, GSII = Glasgow Sleep Impact Index, MHC-SF = Mental Health Continuum - Short Form, HADS-A = Hospital Anxiety Depression Scale — Anxiety, PHQ-9 = Patient Health Questionnaire-9, MPFI-24 = Multidimensional Psychological Flexibility Inventory-24, PSAS = Pre-Sleep Arousal Scale, SRBQ-20 = Sleep-Related Behaviors Questionnaire-20, DBAS-16 = Dysfunctional Beliefs About Sleep-16, BDI-II = Beck Depression Inventory-II, SCID-5-S insomnia = Structured Clinical Interview for DSM-5-Disorders.

Table 3 Outline of ACT-I Sessions.

Session	Topics introduced	Session elements	Homework
			– Intake assignment: describing complaints, sleep effort, sleep rules, short- and long-term effects of trying to control sleep, and potential costs for valued life aspects
Session 1: Creative hopelessness			
1	1) Creative hopelessness 2) Treatment goal: rationale of letting go of the sleep struggle and shifting focus to valuable activities 3) Self-as-context; observing self	a) Practical information and getting acquainted b) Mapping the sleep struggle based on intake assignment c) Metaphor: tug-of-war with a monster d) Introduction of treatment focus e) Exercise: 3-minute meditation f) Introduction to observing self g) Homework	– Daily 3-minute meditation – Reflection assignment: describing the sleep struggle and monitoring moments of sleep struggle
Session 2: Acceptance and towards moves			
2	1) Function of experiential avoidance and sleep struggle 2) Acceptance, willingness to experience as an alternative response to discomfort 3) Towards moves 4) Applying sleep hygiene without sleep struggle	a) Opening meditation b) Homework inquiry c) Discussing the sleep struggle reflection assignment d) Introduction to acceptance e) Metaphor: two switches f) Exercise: experiencing a difficult feeling g) Applying acceptance to day- and nighttime insomnia symptoms h) Introducing towards moves j) Homework, discussing how to apply sleep hygiene without turning it into sleep struggle	– Daily 3-minute meditation – Acceptance exercise – Towards move(s) – Reading sleep hygiene information
Session 3: Defusion from thougths			
3	1) Function of thoughts: the mind wants to keep us safe 2) Unhooking from thoughts based on workability 3) Defusion techniques	a) Opening meditation b) Homework c) Questions about sleep hygiene d) Introducing defusion e) Exercise: I am having the thought that... f) Defusion techniques g) Homework	– Daily 3-minute meditation – Applying acceptance – Defusion exercise – Towards move(s) – Reflection assignment: mapping areas of valued living
Session 4: Values and commited action			
4	1) Rationale of shifting the focus to valuable daytime activities 2) Values and committed action 3) Present moment awareness	a) Opening meditation b) Homework inquiry c) Introducing the shift in focus d) Exercise: sweet spot e) Mapping important life areas f) Exercise: present moment awareness g) Homework	– Daily 3-minute meditation – Diary exercise: savoring meaningful moments – Towards move(s) – Reflection assignment: writing a personal treatment summary
Session 5: Looking back and ahead			
5	1) Personal summary of the most useful skills learned during treatment 2) Relapse prevention	a) Opening meditation b) Homework inquiry c) Discussing diary exercise: savoring meaningful moments d) Discussing personal summary of treatment; how to recognize future sleep struggle, and which skills may help in these moments e) Closing	

Review Board of the University of Amsterdam and registered at Clinicaltrials.gov (NCT06336551). Any modifications to the protocol will be reported.

Measures

Primary outcome. Our primary outcome is insomnia severity at post-assessment relative to pre-assessment, measured with the Insomnia Severity Index (ISI; Bastien et al., 2001). The ISI consists of seven items on insomnia symptoms, each rated on a 5-point scale (range: 0—28), with higher scores indicating more severe insomnia symptoms. The ISI has demonstrated adequate reliability and validity (Bastien et al., 2001). An ISI score reduction of eight or larger will be considered a clinically relevant change and an ISI score smaller than eight at post-assessment will be considered full remission (Morin et al., 2011).

Secondary outcomes. Sleep measures including weekly averages of total sleep time, sleep onset latency, wake after sleep onset, total wake time, sleep efficiency, and sleep quality, are calculated based on the Consensus Sleep Diary (CSD; Carney et al., 2012).

Anxiety symptoms are measured with the Hospital Anxiety and Depression Scale (HADS-A; Zigmond & Snaith,1983), which includes seven items rated on a 4-point scale (range: 0—21), with higher scores indicating more anxiety. The HADS-A has shown good reliability and validity as a symptom screener (Spinhoven et al., 1997).

Depression symptoms are measured with the Patient Health Questionnaire depression scale (PHQ-9; (Kroenke et al., 2001), a nine-item questionnaire scored on a 4-point scale (range: 0—36), with higher scores indicating more depression. The PHQ-9 has shown strong validity and reliability (Kroenke et al., 2001).

General well-being is assessed with the Dutch Mental Health Continuum Short Form (MHC-SF; Lamers et al., 2011), which includes 14 items rated on a 6-point scale (range: 0—70), with higher scores indicating more well-being. The MHC-SF has shown adequate reliability and discriminant validity (Lamers et al., 2011).

Sleep-related quality of life is measured with the Glasgow Sleep Impact Index (GSII; Kyle et al., 2013). In the GSII respondents first define and then rate their three main domains of sleep-related impairment on a visual analogue scale (range: 0—100), with higher scores indicating greater impairment. The GSII has shown excellent construct validity (Kyle et al., 2013).

Psychological (in-)flexibility is measured with the Multidimensional Psychological Flexibility Inventory short form (MPFI-24; Rolffs et al., 2018) a 24-item questionnaire, with two items measuring each of the six dimensions of (in)flexibility, respectively. Scores on psychological (in)flexibility subscales range from 12 to 72, with higher scores indicating more (in)flexibility. The MPFI is regarded as one of the most psychometrically sound measures of ACT dimensions (Ong et al., 2023).

Arousal is assessed with the Pre-Sleep Arousal Scale (PSAS; Nicassio et al., 1985), which includes 16 items scored on a 5-point scale (range: 16—80), with higher scores indicating more arousal. The PSAS has good internal consistency and convergent and discriminant validity (Jansson-Fröjmark & Norell-Clarke, 2012).

Sleep-related safety behavior is measured with the sleep-related behaviors questionnaire short form (SRBQ-20; Lebrun et al., 2020; full scale developed by Ree & Harvey, 2004), which contains 20 items on coping with fatigue or improving sleep, scored on a 5-point scale (range: 0—80), with higher scores indicating more safety behavior. The SRBQ-20 has shown adequate validity and good internal consistency (Lebrun et al., 2020).

Dysfunctional sleep cognitions is measured with the Dysfunctional Beliefs and Attitudes about Sleep Scale short form (DBAS-16; Morin et al., 2007), which includes 16 items rated on an 11-point agreement scale (range: 0—160), with higher scores indicating more dysfunctional cognitions. The DBAS-16 has good psychometric properties (Chung et al., 2016).

Other measures. Demographic information about age, sex assigned at birth and affirmed gender, marital status, education, employment, nationality, medication use (yes/no, room to define), experience with meditation (in years), previously diagnosed psychological disorders, and psychological treatment (yes/no, room to define) is gathered at baseline. During screening the SCID-5 S diagnostic insomnia interview (First et al., 2015/2018) is conducted by a research assistant (clinical psychology graduate student) or a psychologist (first author, ML), both trained and supervised by a health-care psychologist and sleep expert (last author, JL). Compliance with homework is assessed mid- and post-treatment based on self-reported frequencies of practice days. At post-treatment, participants rate their satisfaction with treatment (7-point scale from very unsatisfied to very satisfied, with room to elaborate), their therapist's support (grade from 1 to 10), and whether they would recommend the treatment to others (yes/maybe/no, with room to elaborate). Medication changes and concomitant care (use of additional physical and mental health care) as well as adverse events are measured at mid- and post-assessment, and at follow-ups (yes/no, room to define). Following Linden and Schermuly-Haupt (2014), adverse events include self-reported deterioration of symptoms, emergence of new mental or physical symptoms, occupational problems, and negative changes in social relationships.

ACT-I intervention

The ACT-I intervention consists of five face-to-face individual 60-minute therapy sessions that occur over 7 weeks. The first three sessions are scheduled weekly and the last two sessions are biweekly, to allow more time to incorporate skills towards the end of treatment. The session outline is provided in Table 3.

We developed a detailed ACT-I treatment protocol primarily based on the ACT practitioner's guide by Harris (2019), with additions from A-Tjak (2015) and Jansen and Batink (2014), guided by previous ACT-I protocols (e.g., Rafihi-ferreira et al., 2023). The protocol includes example dialogues and 'what if…' scenarios to tailor to the specific client's needs. We tested the protocol in three small pilots (N = 1, N = 5, N = 6) and consulted sleep- and ACT clinicians in the field for input and feedback during different phases of protocol development.

The ACT-I protocol has two main treatment goals: 1) letting go of the struggle to control sleep and 2) focusing on daytime activities that fit personal values. The first three sessions focus on the first goal, and the last two sessions on the second goal. Treatment goals are addressed through ACT processes of creative hopelessness and self-as-context (session 1), acceptance (session 2), defusion (session 3), followed by values, committed action, and present moment awareness (sessions 4 and 5).

Sessions typically start with an opening meditation and inquiry about the previous week's home practice (15 min). After this, the new topic of the sessions is introduced with an in-session experiential exercise (15 min). Often the topic is related to a homework reflection assignment, and the topic is always discussed in terms of its practical application (15 min). The session ends by discussing the subsequent home practice exercises and stating a 'towards move' to replace a form of sleep struggle, to practice for the coming week (15 min).

The treatment will be delivered by therapists with a clinical psychology master's degree or clinical psychology master students who have completed their clinical internship. All therapists are trained to adhere to the treatment protocol and receive weekly supervision by a licensed ACT therapist (TS) or a healthcare psychologist specialized in sleeping disorders (JL).

All treatment sessions of the ACT-I group are audiotaped, and 20-minute recordings of at least one session per client will be scored on treatment fidelity by independent raters (psychology students), using the ACT treatment fidelity checklist by O'Neill et al. (2019).

Waitlist

The 7-week waiting period consists of completing assessments only. Afterward, the WL group receives ACT-I as well.

Data management

All data will be downloaded from an authorized UvA Qualtrics account and stored in a password-protected research storage folder on a secure server hosted by the UvA. Access is restricted to specifically authorized personnel. After informed consent, participant identifiers are used to ensure anonymity. A separate password-protected folder stores the key file linking identifiers to identifiable information. Contact details will be deleted after publication. Data integrity is safeguarded with forced responses, validation checks, and range checks.

Analysis plan

We will analyze treatment effects on the primary and secondary outcomes based on the intention-to-treat principle, using linear mixed-effect regression models (LMMs) with measurements nested within participants. Models will include fixed effects of group, time, and a group*time interaction. Random effects at the participant level (intercept and/or slope) may be included if this significantly improves model fit. Covariates (i.e., age, sex, gender) will be included if they significantly predict ISI post-scores. We will report the structure of the LMM covariance matrix, estimation method, and 95% confidence intervals, and report analyses with and without outliers (defined as baseline scores > 3 *SDs* from the mean). All analyses will be conducted in R and use two-sided testing with an alpha of .05.

We will analyze proportional group differences of participants achieving a clinical response ($\Delta ISI \geq 8$) or clinical remission (ISI post < 8) using Chi-square tests. Cohen's *d* effect sizes will be reported based on the LMM-estimated mean scores, calculated as the between-group difference in pre-post change scores divided by the pooled standard deviation at baseline (Morris, 2008).

We will use Network Intervention Analysis (NIA; Blanken et al., 2019) to explore the indirect and direct treatment effects of ACT-I compared to WL. Networks will be created at pre-, mid-, and post-assessment and include individual ISI symptoms or ISI total scores together with possible working mechanisms including psychological (in)flexibility, sleep-related arousal, dysfunctional cognitions, and sleep-related safety behaviors. We will only interpret networks with adequate stability, which we will evaluate using bootstrapped samples (*nB* = 1000); the strongest symptom-symptom relations should be included in at least 80% of the samples.

Discussion

The main goal of this RCT is to provide an adequately powered study of the efficacy of stand-alone ACT-I for insomnia. To date, only one RCT has convincingly demonstrated the efficacy of ACT-I without overlapping behavioral components of CBT-I (El Rafihi-Ferreira et al., 2024). More trials are needed to consider stand-alone ACT-I as a distinct alternative when CBT-I is not preferred, not feasible, or proven ineffective. If compared to a waitlist control, ACT-I indeed shows to be efficacious, we encourage further trials to investigate ACT-I's efficacy after unsuccessful CBT-I and to compare the efficacy of ACT-I with and without behavioral components.

Developing and exploring interventions that target insomnia through different treatment paths is crucial to advancing the field. The paths through which ACT-I may achieve therapeutic improvement have been theoretically proposed: by decreasing the controlling relationship with sleep and increasing psychological flexibility (Espie et al., 2006; Rash et al., 2022). Direct tests of ACT-I's treatment mechanisms are, however, still lacking. We aim to take a first step by exploring how ACT-I may directly or indirectly target insomnia through psychological (in)flexibility and maintaining factors of insomnia.

This study can contribute to the understanding of ACT-I's treatment effects and potential working mechanisms. By doing so, we hope this study aids in diversifying the treatment options available for the many individuals struggling with insomnia.

Trial status

Enrollment started in April 2024 and will continue until the summer of 2025. Data collection will be completed in the beginning of 2026.

Data availability

After publication data will be available upon request.

Dissemination of results

We plan to publish results in a peer-reviewed journal regardless of outcomes. After data collection has been completed, participants will receive a Dutch summary of the findings.

Author contributions

TS and JL created the study concept and designed the study together with ML, TB, and JHK. ML, JL, TS, and FL developed and piloted the treatment protocol. ML and JL drafted the manuscript and all authors contributed to and approved the final manuscript. The analysis will be conducted by ML under the supervision of TB and JL.

Author note

An internal research grant from the University of Amsterdam supports this work. The funding source has no role in collecting, managing, analyzing, or interpreting the data, writing the report(s), or deciding to submit the report(s) for publication. The authors declare no conflict of interest.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jbct.2024.100499.

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