Research Paper

Feasibility, acceptability, and preliminary efficacy of an internet-based CBT intervention for loneliness in older adults: A pilot RCT

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A R T I C L E   I N F O

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A B S T R A C T

Background: Older adults are an important target group for loneliness interventions. However, most existing interventions aimed at older individuals do not focus on the strategy that has proven most effective (i.e., modifying maladaptive social cognition). Additionally, given the low mental health service use in this population, innovative treatment approaches are needed in order to provide support to this age cohort. The aim of the current study was to investigate the feasibility, acceptability, and preliminary efficacy of a newly developed internet-based cognitive behavioral therapy intervention for loneliness in older individuals using a pilot randomized controlled trial (RCT).
Methods: In the current study $N = 36$ older adults aged between 65 and 87 years were randomly assigned to either a 7-week internet-based intervention or a wait-list condition. Treatment satisfaction, usability, attrition, and adherence were assessed as indicators for feasibility and acceptability. To investigate preliminary treatment effects, measures on loneliness, depression, anxiety, self-efficacy, and life-satisfaction were administered.
Results: Overall, the intervention program was found to be acceptable and feasible. No significant difference between conditions on loneliness were observed; however, results indicated a trend towards lower reported loneliness levels in the treatment compared to the control group. Regarding secondary outcomes, results pointed at age-specific treatment effects, such that improvements on depression, anxiety, and life satisfaction were observed in the young-old, but not old-old adults in our sample.
Limitations: The sample was small and no follow-up assessment was included.
Conclusions: An internet-based CBT intervention for loneliness seems to be feasible and acceptable in older individuals.

1. Introduction

Loneliness is a worldwide phenomenon affecting millions of individuals around the globe. In the literature, it is usually described as a subjective painful experience arising from a discrepancy among one's desired and actual social contacts (Peplau and Perlman, 1982). While for some, loneliness is a rather transient feeling, it may constitute a chronic and extremely aversive condition for others. Indeed, feelings of loneliness have been found to be a robust risk factor for a number of physical and mental diseases (Hawkley and Capitanio, 2015).

Importantly, loneliness can affect individuals at any age or stage of life (Cacioppo et al., 2015). However, some individuals may be at increased risk for suffering from feelings of loneliness. Indeed, when

looking at the distribution of loneliness along the adult age range, the shape seems to follow a non-linear trajectory with higher loneliness levels observed in younger (< 30 years) and older adults (>70 years) as well as in those aged around 50–60 years (Hawkley et al., 2022). Age itself was not found to be significantly related to loneliness, but rather age differences in predictive factors (e.g., widowhood, poor health) seemed to explain the observed differences (Hawkley et al., 2022). Given these findings, there is a need for effective loneliness interventions particularly for those at older age (besides other affected age groups).

When looking at the intervention literature for loneliness in older individuals, two limitations become evident. First, most loneliness interventions targeting older individuals do not focus on the strategy that

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has proven most effective. Indeed, a meta-analysis by Masi et al. (2011) revealed that cognitive approaches (i.e., addressing maladaptive social cognition) were most effective in reducing loneliness compared to other strategies, such as social support. This finding is also in line with theoretical notions about the role of maladaptive thoughts and beliefs in perpetuating the vicious cycle of loneliness (Cacioppo et al., 2015; Young, 1982). However, most loneliness interventions aimed at older individuals focus rather on other facets, such as social contact (O'Rourke et al., 2018).

Secondly, face-to-face interventions may not constitute the most accepted and feasible treatment approach for this population. When it comes to mental health conditions, only a small proportion of older individuals have been found to seek or receive appropriate treatment (Byers et al., 2012). Several barriers have been identified to impede the provision of psychological treatment to this population, some of which can be overcome by internet-based interventions, such as mobility limitations (Kersting et al., 2009) or stigma (e.g., Cuijpers et al. 2008). With an continuously increasing proportion of older adults using the internet (Hunsaker and Hargittai, 2018) as well as meta-analytical findings proving the efficacy of internet-based interventions in this age cohort (Dworschak et al., 2022), this intervention approach may offer a promising treatment alternative for this population.

To address these gaps in the literature, we developed an internet-based cognitive behavioral therapy (CBT) intervention for loneliness in older individuals (see Dworschak et al. 2023), which will be evaluated for the first time in the current study. There exist three similar intervention programs (Bouwman et al., 2017; Käll et al., 2020; Seewer et al., 2022); however, all of these did not specifically target older individuals (i.e., those aged $\geq$ 65 years), but rather adults in general or middle-aged to older adults (i.e., individuals aged $\geq$ 50 years). As conducting a pilot study prior to a larger randomized controlled trial (RCT) has been described as a crucial step for successful intervention development and evaluation (Thabane et al., 2010), we conducted a pilot RCT primary aimed at exploring the feasibility and acceptability of the newly developed intervention program in older individuals. As a second objective, we were interested in exploratively investigating preliminary treatment effects.

2. Methods

The description of the study follows the CONSORT statement for non-pharmacological trials (Boutron et al., 2008).

2.1. Study design

This study was a pilot RCT where participants were randomly allocated to either an internet-based intervention or a wait-list control group. Outcome measures were collected prior to and after the intervention. Participants in the control group received access to the intervention at the end of the study phase.

2.2. Recruitment and sample

Older adults were recruited using flyers, newspaper articles, online advertisements, the Senior Citizen's University and referrals from another lab study. Advertisements invited older individuals to participate in an internet-based intervention study aimed at reducing feelings of loneliness. Participants were included if they (a) were at least 65 years old, (b) had sufficient German skills, (c) had internet access at least once a week as well as a valid email address, and (d) had a score above 17 on the 9-item short version (Luhmann et al., 2016) of the Revised UCLA Loneliness Scale (Döring and Bortz, 1993; Russell, 1996). The cutoff score for loneliness was derived from two other studies evaluating internet-based loneliness interventions (Käll et al., 2020; Seewer et al., 2022). Individuals were excluded from the study if they reported acute suicidality during (online) screening. Given that loneliness is not

considered a mental disorder and in line with previous studies on loneliness interventions (e.g., Bouwman et al. 2017), no further exclusion criteria with regard to the presence of mental disorders were defined. Study participation was compensated in 20 CHF.

2.3. Procedure

The entire study procedure (including the intervention and outcome assessments) was administered via the same website. Interested individuals first received a detailed description of the study. After submitting informed consent, participants were asked to create a website account and to respond to the screening questions. If participants were found to be eligible for study participation, they were asked to complete the baseline assessment and were then randomly assigned by computer to conditions in a 1:1 ratio. After seven weeks, the post-assessment was administered. For any form of technical issues, an email address and a phone number of the study team were provided. However, in line with the objective of the study, personal contact between participants and the study team was kept at a minimum in order to disentangle effects of the cognitive approach of the intervention from those of social support (e.g., provided by phone calls). Data collection took place between November 2022 and April 2023.

3. Conditions

3.1. Treatment group

Participants in the treatment condition had access to a 7-week internet-based program called "NümEinsam" (Swiss German for "not lonely anymore"). The program was administered via a website and was accessible on a laptop, tablet, or smartphone. The user-centered development of the intervention to tailor it specifically to older adults has been described in detail elsewhere (Dworschak et al., 2023). The intervention was based on CBT and used cognitive restructuring as the main therapeutic technique. In addition, components from positive psychology and life-review therapy were integrated given their beneficial effects on well-being as well as on depression in later life (e.g., Carr et al. 2021; Pinquart and Forstmeier 2012), a mental condition closely tied to the experience of loneliness (e.g., Erzen and Çikrikci 2018). The main focus of the intervention was on identifying and adapting maladaptive thoughts and cognitions associated with loneliness (e.g., Cacioppo et al. 2015). In line with this, the program provided both a theoretical model that was sought to help participants identify and understand their beliefs and behaviors, as well as strategies and behavioral experiments to challenge and question them. The program was a self-guided intervention. No therapist support was provided in order to assess the sole effect of the intervention's CBT approach vs. potential nonspecific effects associated with therapeutic guidance that may be particularly relevant when it comes to lonely individuals (e.g., therapist provides a form of social support which may have a positive impact on individuals' loneliness levels) (Dworschak et al., 2023; Käll et al., 2020).

The treatment program consisted of seven modules focusing on different topics (see Table S1 for an overview). In each module both theoretical explanations as well as practical exercises were integrated that were presented via texts, pictures, audio recordings, or film clips. Participants were encouraged to complete at least one module per week and to follow the sequence of the modules. However, all modules were accessible right from the beginning. Module 6 was introduced as optional (topic "losses"). A fictional e-coach (i.e., a fictional character) guided participants through the program and introduced theoretical explanations as well as practical exercises. Individuals received weekly automated and standardized emails (sent in the name of the e-coach and aimed at increasing motivation). Additionally, users could choose one out of six fictional companions (all aged $\geq$ 65 years) who shared their thoughts and feelings at several points within the modules. The idea of this element was to provide insights into different perspectives and

encourage participants' reflection on key issues raised by the program. Importantly, the mentioned intervention components were specifically designed to address the factors contributing to loneliness that are more prevalent in older age (e.g., widowhood, poorer health; e.g., Hawkley et al. 2022) in several ways (e.g., the fictional characters were designed to experience some of these risk factors such as mobility limitations or widowhood; Module 6 was included to account for the important role of losses in this age cohort; age-appropriate examples were included).

3.2. Wait-list control group

Participants in the wait-list condition received access to the treatment seven weeks after randomization (i.e., after post-assessment).

4. Measures

4.1. Feasibility and acceptability

Treatment satisfaction. Satisfaction with the treatment was measured using the Client Satisfaction Questionnaire for Internet Interventions (CSQ-I; Boß et al. 2016). This questionnaire includes eight items that are rated on a scale from (1) *disagree* to (4) *fully agree*. Sum scores range between 8 and 32 with higher scores suggesting greater satisfaction. Of particular interest were ratings on the perceived quality and relevance of the intervention as well as overall satisfaction with the treatment (questions one, three and seven). Cronbach's alpha was α =0.95 at post-assessment.

Usability. Usability of the internet-based self-help program was assessed using the System Usability Scale (SUS; Brooke 1996). The SUS consists of 10 items assessing the experienced usability of a system/-program. For the current study, the word "system" was adapted to "program" in order to make the items more relevant to the study setting. Items are rated on a five-point scale ranging from (0) *strongly disagree* to (4) *strongly agree*. Total SUS scores (created by recoding reversed items, summing up ratings and multiplying the score by 2.5) range between 0 and 100 with higher scores indicating greater usability. According to Bangor et al. (2009), total SUS scores around 71.4 can be interpreted as *good*, scores around 85.5 as *excellent*. Cronbach's alpha was α=0.78 at post-assessment.

Satisfaction with the intervention title. One additional item was used to assess participants' satisfaction with the title of the intervention. Individuals were asked to rate the item *I like the title of the program ("NümEinsam")* on a scale from (0) *strongly disagree* to (4) *strongly agree* with higher ratings indicating greater satisfaction with the title of the intervention.

Adherence. Adherence was assessed through the number of completed modules. A module was defined as completed if all corresponding pages were visited.

4.2. Preliminary efficacy

4.2.1. Primary outcome
Loneliness. Feelings of loneliness were assessed using the 9-item short version (Luhmann et al., 2016) of the Revised UCLA Loneliness scale (Döring and Bortz, 1993; Russell, 1996). The original scale consists of 20 items and assesses three distinct factors of loneliness: intimate, relational, and collective loneliness (Hawkley et al., 2005). Based on the factor loadings, the short form uses only the three items with the highest loading on each loneliness facet. The scale assesses loneliness indirectly (i.e., the term "lonely" is not used). Items are rated on a four-point scale ranging from (1) *never* to (4) *always*. Sum scores can range from 9 to 36 with higher scores indicating greater feelings of loneliness. Cronbach's alpha was α=0.76 at baseline and α=0.81 at post-assessment.

4.2.2. Secondary outcomes
Depressive symptoms. Depressive symptoms were assessed using the Patient Health Questionnaire for Depression (PHQ-9; Kroenke et al. 2001; Löwe et al. 2004). The PHQ-9 includes nine items that are rated on a four-point scale ranging from (0) *not at all* to (3) *almost daily*. Sum scores can range between 0 and 27 with higher scores indicating greater depression severity. Cronbach's alpha was α=0.60 at baseline and α=0.81 at post-assessment.

Symptoms of anxiety. Symptoms of anxiety were assessed using the Generalized Anxiety Disorder Screener (GAD-7; Löwe et al. 2008). The GAD-7 consists of seven items that are rated on a four-point scale ranging from (0) *not at all* to (3) *almost daily*. Sum scores range between 0 and 21 with higher scores indicating greater anxiety severity. Cronbach's alpha was α=0.80 at baseline and α=0.84 at post-assessment.

Self-efficacy. Self-efficacy was assessed using the General Self-Efficacy Scale (GSE; Schwarzer and Jerusalem 1999). The GSE includes 10 items that are rated on a scale from (1) *not at all true* to (4) *exactly true*. Sum scores range between 0 and 40 with higher scores indicating greater self-efficacy. Cronbach's alpha was α=0.89 at baseline and α=0.91 at post-assessment.

Satisfaction with life. Satisfaction with life was measured using the satisfaction with Life Scale (SWLS; Diener et al. 1985; Schumacher 2003). The scale consists of five items that are rated on a seven-point scale ranging from (1) *strongly disagree* to (7) *strongly agree*. Sum scores range from 5 to 35 with higher scores indicating greater satisfaction with life. Cronbach's alpha was α=0.85 at baseline and α=0.86 at post-assessment.

5. Sample size

As this was a pilot RCT primarily aimed at testing the feasibility and acceptability of the intervention, a formal calculation of the sample size was not conducted. However, we decided to estimate the required sample size as around 20–25 % of the number of participants needed for the future RCT. Aiming to detect a moderate standardized mean difference effect size at post-assessment ($d = 0.50$) with a power of 80 % at a two-sided alpha level of 0.05, 128 participants would be required for the future RCT. We therefore aimed to recruit a sample of around 25–32 participants for the current pilot RCT. Thus, the sample in the current study was not aimed at and powered for detecting significant differences between conditions.

6. Statistical analyzes

Statistical analyzes were conducted using the statistic software R version 4.2.2 (Core Team, 2022). Parametric tests were used given that all study variables were found to be normally distributed at both baseline and postassessment (see Table S2) and sample size was larger than the minimal sample size recommended for parametric testing (>29) (Chin et al., 2008). *t*-tests and chi-square tests were used to test for differences between conditions as well as between completers/non-completers of post-assessment. In line with the first aim of the study, namely testing the feasibility and acceptability of the intervention, descriptive statistics were used to analyze attrition, adherence, and treatment acceptance. The second objective of the study was to investigate preliminary treatment effects. It is important to mention here, that given the rather non-confirmatory design of the current study, it was not powered to detect significant differences and, hence, analyzes regarding the preliminary efficacy were rather explorative. To this aim, analyzes were conducted based on the intention-to-treat principle. Linear mixed effect models were calculated given their ability to handle missing data through maximum likelihood estimation (Graham, 2009) using the R package *nlme* (Pinheiro and Core Team, 2022; Core Team, 2022). Group (wait-list vs. treatment), time (baseline vs. post-assessment) and the interaction of group by time were entered into the model as fixed factors, subject as a random factor, and continuous outcomes as dependent variables in separate models (referred to as *main models*). The wait-list condition was coded as 0 and

treatment condition as 1. After calculating the main models, control variables (age, sex, currently in psychotherapy [yes/no]) were entered consecutively as main and interaction term with group and time (three-way interaction term of group by time by control variable) in separate models. Age was grand-mean centered. Indication for a preliminary treatment effect was determined by a significant group by time or group by time by control variable interaction. In the results section, it is noted only if entering a control variable to the model changed results of the main model or resulted in a significant three-way interaction. Significant interaction effects were followed-up by running simple slope analyzes. Cohen's d was calculated as effect size based on observed means within groups (baseline to post-assessment) and between groups (at post-assessment). Based on Cohen (1992), $d = 0.2$ can be interpreted as a small, $d = 0.5$ as a medium, and $d = 0.8$ as a large effect. Given the rather explorative character of the analyzes, we followed recommendations of Bender and Lange (2001) and did not adjust for multiple testing.

7. Results

7.1. Participant flow, baseline characteristics and participant contacts

Fig. 1 shows the flow of participants through the trial. There were no significant differences between conditions with regard to demographics (Table 1) or baseline outcome measures (Table 2; all $p > 0.163$). Contact with participants was kept at a minimum; during study procedure, participants predominantly reached out via email (vs. phone) and most requests concerned technical issues or questions about the study.

8. Feasibility and acceptability

8.1. Attrition, treatment adherence, and missing data

Attrition was low as overall only one participant in the intervention group decided to withdrew consent during the treatment period. Participants in the treatment condition completed an average of $M = 4.28$ ($SD = 2.30$) out of seven modules with one module being an optional one. Furthermore, 44.44 % ($n = 8$) of participants in the treatment group completed at least six modules. The partial correlation between the number of completed modules and loneliness scores at post-assessment, controlling for baseline scores, was not significant ($r = 0.27$, $p = .347$). A total of 28 older adults (77.78 %) across groups completed the post-assessment. One participant in the treatment condition provided an incomplete post-assessment. However, as all measures for primary and secondary outcomes were completed, we did not define this subject as a non-completer. Completers and non-completers of the post-assessment did not differ significantly with regard to demographic and baseline characteristics (Table S3). Three (16.67 %) participants in the treatment and four (22.22 %) participants in the wait-list condition indicated at baseline, that they were currently in psychotherapy.

8.2. Treatment satisfaction and usability

Fifteen (83.33 %) participants in the treatment condition responded to the items of the CSQ-I. Regarding the questions of primary interest, 93.33 % ($n = 14$) agreed that the quality of the intervention was high (numbers refer to the number of participants choosing (3) *agree* or (4) *fully agree* as answer). Sixty percent ($n = 9$) indicated that the program met their needs and 66.67 % ($n = 10$) reported overall satisfaction with the intervention. Sum scores on the CSQ-I ranged from 10 to 32 with a
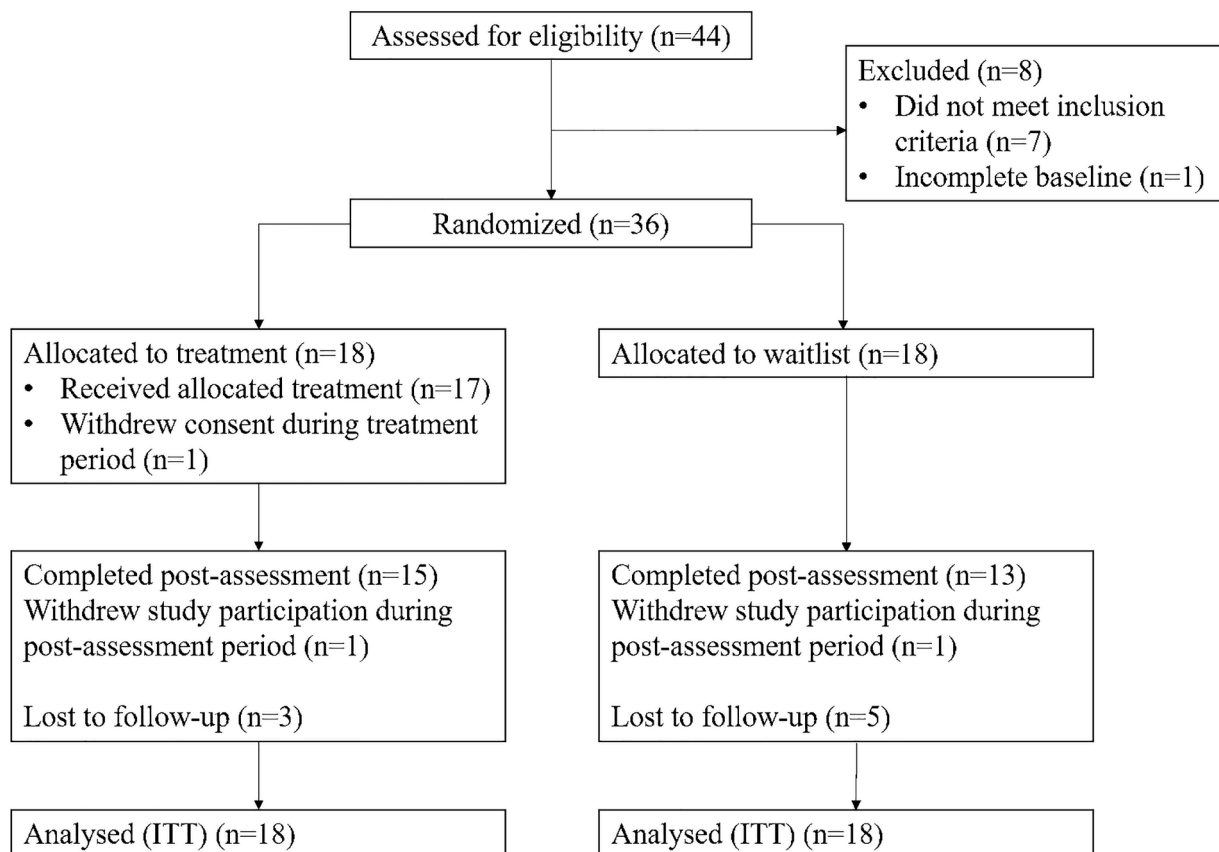

Fig. 1. Flow diagram of participants in the study
Notes. ITT = intention-to-treat principle.

Table 1
Sample Characteristics.

Demographic characteristic		Treatment Group ($n = 18$) n (%) M (SD)	Wait-list ($n = 18$) n (%) M (SD)	Test statistics
Age		70.83 (5.50)	72.06 (6.28)	$t(34)=-0.62$, $p=.539$
Sex				$\chi^2(1)=0$, $p = 1.0$
	Male	5 (27.78 %)	4 (22.22 %)	
	Female	13 (72.22 %)	14 (77.78 %)	
Nationality				
	Swiss	18 (100 %)	18 (100 %)	
Education				$\chi^2(5)=3.74$, $p=.587$
	Compulsory school	1 (5.56 %)	0 (0 %)	
	Apprenticeship	3 (16.67 %)	7 (38.89 %)	
	High school	1 (5.56 %)	2 (11.11 %)	
	Higher professional education	7 (38.89 %)	5 (27.78 %)	
	University	4 (22.22 %)	3 (16.67 %)	
	Not stated	2 (11.11 %)	1 (5.56 %)	
Current Professional Situation				$\chi^2(3)=3.03$, $p=.387$
	Retired (fully)	16 (88.89 %)	17 (94.44 %)	
	Retired (partly)	0	1 (5.56 %)	
	Employed	1 (5.56 %)	0 (0 %)	
	Self-employed	1 (5.56 %)	0 (0 %)	
Marital Status				$\chi^2(4)=5.29$, $p=.259$
	Married	2 (11.11 %)	4 (22.22 %)	
	Single/Never married	8 (44.44 %)	2 (11.11 %)	
	Separated	1 (5.56 %)	2 (11.11 %)	
	Divorced	5 (27.78 %)	8 (44.44 %)	
	Widowed	2 (11.11 %)	2 (11.11 %)	
Children				
	Yes	6 (33.33 %)	12 (66.67 %)	$\chi^2(1)=2.78$, $p=.096$
	Number of Children	1.67 (1.03)	2 (0.74)	$t(16)=-0.79$, $p=.440$
Currently in psychotherapy				

Table 1 (*continued*)

Demographic characteristic		Treatment Group ($n = 18$) n (%) M (SD)	Wait-list ($n = 18$) n (%) M (SD)	Test statistics
	Yes	3 (16.67 %)	4 (22.22 %)	$\chi^2(1)=0$, $p = 1.0$
Non-completers post-assessment		3 (16.67 %)	5 (27.78 %)	$\chi^2(1)=0.16$, $p=.689$

mean of $M = 22.60$ ($SD=7.10$). There was a significant negative partial correlation between CSQ-I sum scores and loneliness scores at post-assessment controlling for baseline levels, such that a greater satisfaction with the intervention was associated with lower loneliness levels at post-assessment ($r=-0.64$, $p=.014$). Fourteen (77.78 %) older adults of the treatment group provided data regarding the usability of the internet-based program and the satisfaction with the title. Total SUS scores ranged from 47.50 to 100 with a mean score of $M = 80$ ($SD=16.41$), which can be interpreted as *good* to *excellent* (Bangor et al., 2009). The partial correlation between the SUS score and loneliness scores at post-assessment while controlling for baseline scores was nonsignificant ($r=-0.48$, $p=.098$). Fifty percent ($n = 7$) reported that they liked the title of the intervention, while 28.57 % ($n = 4$) were neutral about it.

9. Preliminary efficacy

Table 2 shows means and standard deviations of the baseline and post-assessment as well as effect sizes (Cohen's d) for outcome measures. Table 3 depicts results on the fixed effects of the main models (mixed linear models); random effect results can be found in Table S4.

9.1. Primary outcome

Although a small between-group effect was observed on the UCLA favoring the treatment group over control condition (Table 2), the main model did not reveal a significant group by time interaction (Table 3). The addition of control variables to the model did not result in any significant changes.

9.2. Secondary outcomes

The between-group effect size for the PHQ-9 was negligible (Table 2) and no significant group by time interaction was found in the main model (Table 3). However, when age was added, the three-way interaction term of group by time by age revealed as significant ($B = 0.51$, $SE=0.23$, CI 0.07 to 0.96, $p=.036$). Simple slope analyzeanalyzes tested slopes for young-old ($M_{age} - 1$ SD = 65.63 years), middle-old ($M_{age} = 71.44$ years) and old-old adults ($M_{age} + 1$ SD = 77.26 years) in our sample. These analyzes showed that, among young-old adults, improvements on depressive symptoms were at the threshold of significance in the treatment ($B=-2.51$, $SE=1.23$, $p=.053$), but not in the wait-list condition. However, among old-old adults, the opposite pattern was observed, such that a significant reduction in depression levels was found in the wait-list ($B=-3.48$, $SE=1.21$, $p=.008$), but not in treatment group. No significant effects were observed among middle-old adults.

Regarding the GAD-7, the between-group effect size was negligible (Table 2) and main models revealed no significant group by time interaction (Table 3). However, when age was entered, a significant three-way interaction effect of group by time by age was found ($B = 0.49$, $SE=0.21$, CI 0.08–0.91, $p=.030$). Simple slope analyzes showed that, among young-old adults, there was a significant reduction in

Table 2
Means, SDs, and effect sizes (Cohen's d) for outcome measures.

		Baseline			Post-assessment			Cohen's d	
		Mean	SD	n	Mean	SD	n	Within-group, bl-post	Between-group, post
UCLA	Treatment	25.89	3.41	18	21.87	4.10	15	0.64	0.29
	WL	24.28	3.39	18	23.00	3.67	13	0.82	
PHQ-9	Treatment	8.78	3.28	18	7.20	3.93	15	0.44	0.15
	WL	9.72	3.46	18	7.92	5.66	13	0.40	
GAD-7	Treatment	7.39	3.42	18	5.13	3.29	15	0.67	0.14
	WL	7.33	4.41	18	5.69	4.55	13	0.37	
GSE	Treatment	26.67	5.02	18	29.33	3.58	15	0.60	0.16
	WL	25.56	5.86	18	28.54	6.25	13	0.49	
SWLS	Treatment	18.83	5.72	18	20.07	5.86	15	0.21	0.32
	WL	18.94	6.18	18	22.08	6.56	13	0.49	

Note. WL = Wait-list; UCLA = 9-item short version of the Revised UCLA Loneliness scale; PHQ-9 = Patient Health Questionnaire for Depression; GAD-7 = Generalized Anxiety Disorder Screener; GSE = General Self-Efficacy Scale; SWLS = Satisfaction with life scale; bl = Baseline; post = Post-assessment.

Table 3
Results of linear mixed model analyzes (main models) ($N = 36$).

Outcome	Time				Group x Time Interaction			
	B	SE	95 % CI	p	B	SE	95 % CI	p
UCLA	-2.81	1.06	-4.92, -0.70	.013	0.35	1.46	-2.55, 3.26	.812
PHQ-9	-1.74	1.04	-3.82, 0.33	.107	-0.03	1.43	-2.88, 2.83	.986
GAD-7	-1.63	1.02	-3.65, 0.40	.122	-0.88	1.40	-3.67, 1.90	.533
GSE	2.21	0.94	0.36, 4.08	.027	0.62	1.29	-1.95, 3.18	.637
SWLS	2.19	1.21	-0.21, 4.59	.080	-0.64	1.65	-3.94, 2.65	.700

Note. The B estimate is the unstandardized regression coefficient. UCLA = 9-item short version of the Revised UCLA Loneliness scale; PHQ-9 = Patient Health Questionnaire for Depression; GAD-7 = Generalized Anxiety Disorder Screener; GSE = General Self-Efficacy Scale; SWLS = Satisfaction with life scale.

anxiety symptoms in the treatment (B=-5.81, SE=-2.96, p=.016), but not in the wait-list condition. The same pattern was observed among middle-old adults (treatment condition: B=-2.51, SE=0.86, p=.008). However, among old-old adults, the opposite pattern was found, such that a significant effect on anxiety levels was observed in the wait-list (B=-3.62, SE=1.11, p=.003), but not in the treatment condition.

For the GSE, the between-group effect size was negligible (Table 2) and we did not find a significant group by time interaction in the main model (Table 3).

With regard to the SWLS, Cohen's *d* indicated a small between group effect size favoring wait-list over treatment condition (Table 2) and no significant group by time interaction was found in the main model (Table 3). However, when age was added, the three-way interaction term of group by time by age revealed as significant (B=-0.68, SE=0.26, CI -1.18 to -0.18, p=.015). Simple slope analyzes indicated that among young-old adults, there was a significant increase in life satisfaction in the treatment (B = 4.01, SE=1.38, p=.008), but not in the control condition. Among old-old adults, the opposite pattern was found, such that a significant increase in life satisfaction was observed among the wait-list (B = 2.95, SE=1.36, p=.039), but not the treatment condition. No significant effects were found among middle-old adults.

10. Follow-up descriptive analyzes on age differences

Given the identified significant three-way interactions between group, time, and age on some secondary outcome measures, we were interested in investigating whether there were any systematic differences between younger and older old participants in our sample with regard to baseline assessments, treatment satisfaction, and adherence, that could potentially contribute to a more fine-grained understanding of these findings (e.g., some studies have pointed at age differences in adherence to internet-based interventions; Japuntich et al. 2006; Verheijden et al. 2007). Therefore, as follow-up analyzes, we exploratively calculated correlations between age and baseline measures, treatment satisfaction, and adherence. analyzes revealed a significant correlation

between age and SWLS scores at baseline, such that higher age was associated with greater life satisfaction (r = 0.39, p=.020). All other correlations were nonsignificant (all p > .259). Results can be found in the supplementary material (Table S5).

11. Discussion

The aim of the current study was to investigate the acceptability, feasibility, and preliminary efficacy of a newly developed internet-based intervention for loneliness in older individuals. To the best of our knowledge, this study is the first in evaluating such an intervention in a population of older individuals.

12. Summary of findings

12.1. Feasibility and acceptability

Overall, the intervention program was found to be acceptable and feasible in the group of older individuals. With regard to adherence and dropout, participants completed an average of M = 4.28 (SD=2.30) out of a total of seven modules (including one optional module) and 25 % of participants did not complete the post-assessment. Studies on similar loneliness interventions conducted in the general adult population or in middle-aged to older adults have reported slightly lower average treatment use and higher dropout rates (Bouwman et al., 2017; Käll et al., 2020, 2021). This observed difference to other studies is in line with previous research indicating higher adherence to internet-based interventions in those at older vs. younger age (e.g., Japuntich et al. 2006; Verheijden et al. 2007). Alternatively, the lower dropout rates observed in the current study could also be due to the fact that participants were compensated for filling out the postassessment questionnaires.

With regard to treatment satisfaction, the majority of participants indicated overall satisfaction with the treatment and rated the quality of the program as high. The mean sum score of the CSQ-I was M = 22.60 (SD=7.10), which was comparable to mean sum scores on a similar CSQ

questionnaire reported in two other studies evaluating an internet-based loneliness intervention ($M = 23.96$ [SD=4.67] reported in Käll et al. 2020; $M = 23.89$ [SD=5.51] reported in Käll et al. 2021). Further, based on Bangor (2009), usability of the program could be interpreted as *good* to *excellent*. These findings are in line with previous studies evaluating internet-based interventions in older individuals reporting high treatment satisfaction and acceptance (e.g., Titov et al. 2016). The observed high usability of the intervention may also be due to the user-centered development of the intervention including a usability testing with potential end users (Dworschak et al., 2023). This highlights the relevance of including target users in the development process of an intervention to ensure a high level of usability.

12.2. Preliminary treatment effects

In terms of the primary outcome loneliness, we did not find a significant difference between groups; however, results indicated a trend towards lower reported loneliness levels at post-assessment in the treatment compared to the control condition. On the one hand, as generally effects of loneliness interventions seem to be rather small in randomized group designs (Masi et al., 2011), we might simply not have been able to detect significant differences given our small sample size. Alternatively, previous research using a sample of individuals aged 50 years and older has also revealed differences in prevalence rates of loneliness when using direct vs. indirect measures (Shiovitz-Ezra and Ayalon, 2012). Indeed, 57 % of participants reporting being lonely on a direct measure were defined as *not lonely* when using an indirect questionnaire. Thus, given the use of a solely indirect loneliness measure in this study, we might not have been able to fully capture loneliness. Future intervention studies should include both a direct and an indirect measure of loneliness to shed light on the role of different kinds of measure approaches when evaluating treatment effects.

Interestingly, when looking at within-group effect sizes for loneliness, we observed a larger effect size for the wait-list compared to the treatment group. This suggests that control participants may have experienced improvements similar to or even more than treatment participants; thus, implying that the intervention needs to be improved further. However, the lower observed loneliness scores at postassessment in the treatment compared to the control group, the between-group effect direction and size as well as the results on secondary outcomes speak to the beneficial effects of the intervention program. Evaluating the intervention program in a larger sample is urgently needed to clarify the efficacy of the newly developed treatment.

With regard to secondary outcomes, models revealed no significant differences between treatment and wait-list condition. However, when age was added, significant (or at the threshold of significance) treatment effects were observed among young-old ($M_{age} - 1$ SD = 65.63 years), but not old-old adults ($M_{age} + 1$ SD = 77.26 years) on depression, anxiety, and life satisfaction. Significant intervention effects in middle-old adults ($M_{age} = 71.44$ years) were only observed in the model predicting anxiety. Interestingly, a similar pattern with decreasing effects with age was observed in a meta-analysis summarizing effects of studies on internet-based CBT for late-life depression (Xiang et al., 2020). The authors named developmentally unadjusted treatments as one potential explanation. Importantly, the program used in this study was developed involving older adults in order to tailor it to this population. However, findings suggest that there still may be significant developmental differences within the group of older adults, namely between younger and older old adults, that have to be taken into account when developing interventions for this population. Further research, especially in larger samples, is needed to fully understand potential age differences in treatment effects of internet-based interventions and to shed light on the underlying mechanisms.

Surprisingly, among old-old adults, a significant positive effect on depression, anxiety, and life satisfaction was observed in the wait-list condition. Indeed, previous research has revealed spontaneous psychological symptom remission in wait-list participants in controlled trials (e.g., Posternak and Miller 2001). When investigating the moderation of age, a meta-analysis by Hesser et al. (2011) on tinnitus distress treatment found smaller effect sizes with advancing age in the waiting condition. On the other hand, some research suggests that, generally, expectancy for positive events increases with age (Steinman et al., 2013). Given these ambiguous findings, more research is needed to capture the role of age in wait-list and expectancy effects.

Interestingly, we did not find a significant treatment effect on self-efficacy, which could be due to the small sample size and has to be further investigated in the main RCT. However, some researchers have also questioned the possibility of modifying self-efficacy beliefs in older adults (FitzGerald et al., 2022). The authors argued that given the profound impact of lifetime experiences on self-efficacy (Rovniak et al., 2002), it might be particularly more difficult for older (vs. younger) adults to change beliefs that have been built over decades. After searching the literature, FitzGerald et al. (2022) found only 7 out of 20 intervention studies reporting increases in self-efficacy in older individuals. The authors concluded that, while it seems somehow possible to modify self-efficacy in older adults, the actual extent to which this is possible remains unclear and has to be further investigated.

13. Limitations

The present study has limitations. First, this study was not preregistered. Second, sample size was small, limiting our statistical power to detect small effects. Third, the lack of general guidelines and norms for evaluating treatment satisfaction as measured with the CSQ-I reduces our ability to interpret and classify results. Fourth, given that no follow-up assessment was included, the long-term effects of our intervention remain unclear and have to be subject to further investigation. Fifth, given the lack of data on the amount (e.g., for how long, intensity of use) and period of time (e.g., only at the beginning of the study period) participants used the intervention program, final conclusions regarding treatment adherence remain limited. Lastly, given that no data on the use of and satisfaction with individual modules was collected, it remains unclear which modules were most relevant and helpful to participants. However, we hope to investigate this in future studies.

14. Conclusion

The aim of this study was to evaluate the feasibility, acceptability, and preliminary efficacy of a newly developed internet-based CBT intervention for loneliness in older individuals. The treatment program was found to be feasible and acceptable. Regarding the preliminary efficacy, findings are promising and point at age-specific treatment effects for secondary outcomes with improvements observed in young-old, but not old-old adults. Findings of the current study provide important insights for the future RCT and add valuable knowledge about the feasibility and acceptability of such an intervention in older adults.

CRediT authorship contribution statement

Christine Dworschak: Conceptualization, Methodology, Investigation, Formal analysis, Data curation, Writing – original draft, Project administration, Funding acquisition. **Eva Heim:** Conceptualization, Methodology, Supervision, Writing – review & editing. **Alicia Tröster:** Investigation, Formal analysis, Writing – review & editing. **Chantal Grunder:** Investigation, Formal analysis, Writing – review & editing. **Andreas Maercker:** Conceptualization, Methodology, Supervision, Writing – review & editing, Funding acquisition.

Declaration of Competing Interest

Acknowledgments

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jadr.2023.100692.

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