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Efficacy of the I-SOCIAL intervention for loneliness in old age: Lessons from a randomized controlled trial

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ABSTRACT

Loneliness is common among older persons and is associated with adverse health and wellbeing outcomes. We investigated a theory-based intervention that addresses barriers to social contacts and aims at increasing social self-efficacy. Individuals that met pre-assessment criteria of cognitive function, physical health, and loneliness levels were randomly assigned either to the I-SOCIAL intervention that combined both individual and group sessions to address individuals' unique social challenges, or to the control group. Assessment was administered at baseline, after the completion of the intervention, and after a 3-month follow-up period. The intervention group showed significant decline in loneliness level compared to the control group, both after the intervention and after the follow-up period. This innovative combination of analysis of personal barriers, support provided by the counselors, group activities, and individualized suggestions for social activities in the participant's neighborhood, may account for the success of the intervention in decreasing participants' loneliness levels.

1. Introduction

Loneliness has long been recognized as a persistent problem among older populations, with reported prevalence ranging from 10% to 45% of older persons depending on their gender, age group, and method of assessing loneliness (Brodsky et al., 2017; Cohen-Mansfield et al., 2009; Niedzwiedz et al., 2016). It generally refers to the person's subjective experience of inadequate quality or level of relationships (Lopata, 1969; Russell et al., 1984; Weiss, 1973). In contrast to loneliness, "social isolation" refers to the objective aspect of limited social interactions. (Chappell and Badger, 1989; de Jong Gierveld et al., 2018; Dykstra, 2009; Weiss, 1973; Wenger et al., 1996).

Multiple factors affect loneliness in older adults. A review of correlates (Cohen-Mansfield et al., 2016) found demographic variables such as female gender, non-married status, older age, and poor income to be related to higher levels of loneliness. Psychological attributes such as poor mental health, low self-efficacy beliefs, cognitive deficits, as well as social attributes (e.g. quality and quantity of social networks) and medical and functional status, were also associated with loneliness. Furthermore, limited financial resources and insufficient opportunities for social contact were found to be significant predictors of loneliness (Cohen-Mansfield and Parpura-Gill, 2007). Successful social integration is dependent on an appropriate environment and on adequate social skills (de Jong Gierveld et al., 2018).

Creating avenues for social integration for those who have difficulty fulfilling their social needs is of paramount clinical significance for preventing the adverse outcomes of loneliness (Heinrich and Gullone, 2006). Reported negative outcomes of loneliness include poor overall health, higher blood pressure (Luanaigh and Lawlor, 2008), coronary issues (Sorkin et al., 2002), depressed affect, faster cognitive deterioration (Donovan et al., 2017; Golden et al., 2009), as well as Alzheimer's disease (Wilson et al., 2007), poor quality of life (Chalise et al.,

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2010; Paul et al., 2006), and increased mortality rates (Penninx et al., 1997; Seeman, 2000; Shiovitz-Ezra and Ayalon, 2010; Sugisawa et al., 1994).

Intervention studies which aimed to decrease loneliness have been based on either group or individual formats, and they involved different kinds of content, such as psychological help, (e.g. social skills training), recreational activities (such as art or exercise), or practical help (e.g., using hearing aids). Furthermore, although various interventions seem promising, their efficacy was questionable due to flawed research designs (Cohen-Mansfield and Perach, 2015), and they have been unable to provide conclusive evidence (Cattan et al., 2005).

The current study addresses limitations of past studies in several ways. First, the intervention developed for this study, the Increasing SOcial Competence and social Integration of older Adults experiencing Loneliness (I-SOCIAL) intervention, is theory-based. It is grounded in the general framework of a Cognitive-Behavioral theoretical model, conceptualizing behaviors as resulting from the interaction between personal and environmental factors, as well as being based on the MOdel of DEpression and Loneliness (MODEL), which identified specific barriers to social integration among lonely older individuals (Cohen-Mansfield and Parpura-Gill, 2007). Second, the intervention integrates individual and group sessions. Third, we aimed to decrease the methodological flaws by conducting a randomized controlled trial.

2. Methods

2.1. Participants

We recruited 136 potential participants from many sources, including two local branches of a Health Maintenance Organization (HMO; 36 participants), calling people from a list of local older persons purchased from a commercial vendor (36 participants), local senior centers and university lectures open to the public (19 participants), persons referred from other studies or through other participants of this study (13 participants), responses to posters advertising the study (13 participants), referrals from the municipal social service agency (12 participants), and local residential buildings for older persons (7 participants). A total of 89 persons were randomized (44 = control, 45 = intervention, i.e., receiving the I-SOCIAL intervention); of these 74 participants completed the intervention (35 = control, 39 = intervention), and 63 completed follow-up (28 = control, 35 = intervention). A flow diagram presenting recruitment and exclusions of potential participants is presented in Fig. 1. Participants' demographic characteristics are described in Table 1.

2.2. Assessments

Pre-intervention questionnaire. ***Demographic information*** included gender, age, marital status, place of birth, and years of education. ***Health*** was assessed by number of medical diagnoses. ***Subjective health*** was rated on a 4-point scale (poor, fair, good, excellent). ***Cognitive function*** was assessed using the validated Hebrew version of the Mini Mental State Examination (Folstein et al., 1975; Werner et al., 1999). The total score ranges from 0 (severe cognitive impairment) to 30 (normal cognitive functioning).

Outcome variable. ***Loneliness*** was assessed by three measures: (a) The UCLA Loneliness Scale- 8 items (ULS-8; Hays and DiMatteo, 1987). Each item was rated on a 5-point scale from "not at all" (1) to "to a great extent" (5), with a higher score indicating greater loneliness. The rating scale of two items, "I am an outgoing person" and "I can find companionship when I want it" was reversed. Based on experience from another study (Cohen-Mansfield et al., 2015), "I am unhappy being so withdrawn" was replaced with two items: "I feel physically distant from other people" and "I feel emotionally distant from other people"; (b) ***Frequency of loneliness*** was measured via "How often would you say you feel lonely?" (Mullins et al., 1990) on a 6-point scale from "never" (1) to "several times an hour" (6); (c) ***Severity of loneliness*** (Holwerda et al., 2014) was measured via "To what extent do you feel lonely?" measured on a 5-point scale from "not at all" (1) to "to a very large extent" (5). The three measures were highly inter-correlated, with correlations at baseline ranging from $r = .50$ to $r = .65$ with sample sizes ranging from 117 to 132, $p < .001$. We therefore used the mean of the three measures (after transforming the frequency measure to a 1–5 range to equalize its weight to the other two measures) as the outcome variable for the study.

2.3. Procedure

The ethics committee of Tel-Aviv University approved the study as did the Helsinki ethics committee of Meir Medical center. The study was registered at ClinicalTrials.gov (identifier NCT01842984). Inclusion criteria were (1) age 65 and above; (2) feeling lonely based on the questions of degree (moderate level and above) and frequency (several times a week and above) of loneliness on the screening questionnaire, as well as not participating in social activities and expressing at least moderate desire to have additional company; (3) being able to participate based on cognitive function (MMSE > 22); (4) no significant depression as screened by the Geriatric Depression Scale (GDS). We used a cut-off of 10, which indicates moderate depression.

All individuals recruited were interviewed in-person by a research assistant to complete the pre-intervention questionnaire, which included items on background information: demographic, cognitive function, physical health, as well as on loneliness. Written informed consent was obtained at pre-intervention interview. Participants were also interviewed at the end of the intervention about six months after the baseline pre-intervention interviews (5.65(1.55) with a range of 3.20–9.00 months), and at end of a three-month follow-up period (3.09(.31) with a range of 2.40–4.07 months).

The study was conducted in three waves, and in each, we went through all the stages of the study including assessments, intervention, and control groups. At the end of the intervention process, the participants completed the assessment, and they were asked again to do so at the end of the three months' follow-up period. Post-intervention questionnaires were administered by a research assistant who was not associated with the interventions, thus decreasing the likelihood of a social desirability bias.

Intervention. The I-SOCIAL intervention is based on findings from Cohen-Mansfield and Parpura-Gill (2007), which highlighted the role of barriers in producing and maintaining loneliness in older persons. The intervention focused on addressing psychosocial barriers, such as low social self-efficacy, and environmental barriers, such as lack of social opportunities in the vicinity of the older person. The intervention included: (1) identifying the barriers for the specific person; (2) up to ten individual meetings with an activities counselor, which focused on helping the person address personal barriers to social integration and included discussions concerning options for social contacts as well as using techniques and local resources to tackle the barriers (e.g., undertaking a mapping of social opportunities in the neighborhood using resources from local governments and senior centers); and (3) up to seven group sessions of participants and the activities counselors were held in order to provide opportunities to increase social competence by practicing social skills within a protected setting, and as a venue to discuss barriers and ways to address them. The participants chose whether to partake in the individual meetings, the group sessions, or both. The rationale for including both individual and group sessions was based on our pilot work that found that some lonely persons were not comfortable in groups or initially not willing to participate in groups, and that individual meetings would allow us to work on barriers and solutions particular to each individual. In contrast, the group sessions allowed participants to practice and share solutions with each other. The activities counselors in this study had at least a Bachelor's degree in the social sciences. Prior to the intervention, the activities

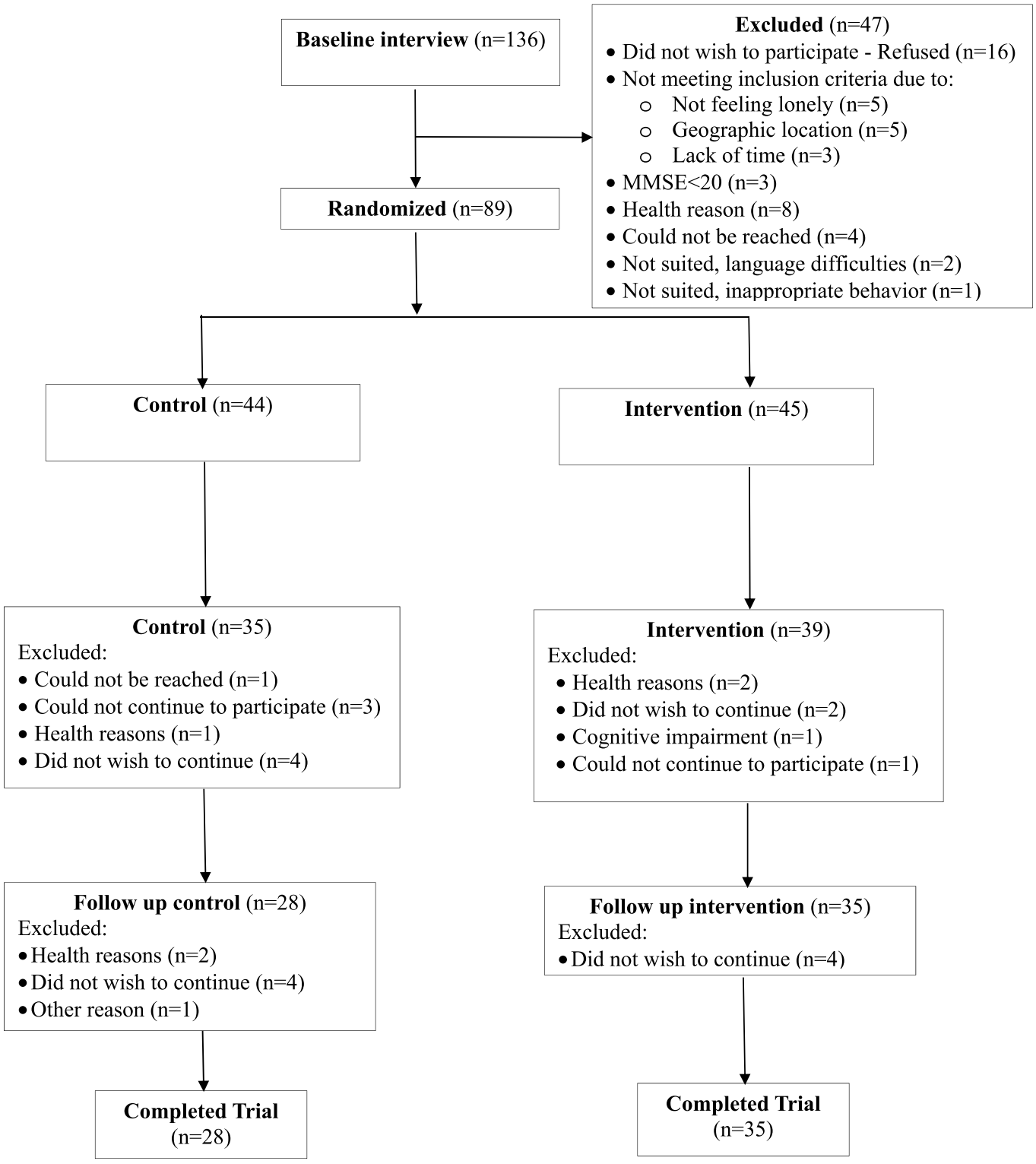

Fig. 1. Participants' flow chart.

counselors received training in motivational interviewing and in the principles of cognitive behavior therapy, and they were introduced to the principles and the model of the intervention. During the intervention, they summarized the activities after each individual and group session and received at least one hour of supervision a week.

Control. Participants in the control group received no social engagement nor help in promoting social engagement from the research staff.

2.4. Statistical analysis

The results were analyzed with a repeated measures analysis of variance (ANOVA). Group (intervention vs. control) was the between-subjects factor and time was the within subject factor. Because of the relatively small sample size and the decreasing size at follow-up, we conducted two repeated measures ANOVAs, one at the end of intervention and one at follow-up. In addition, in order to examine the

Table 1
Comparison of intervention vs. control group.

	Intervention group (n = 39)	Control group (n = 35)
	Mean (SD)/n	
Demographics		
Gender – Women	31	29
Age	76.6 (6.8)	79 (6.62)
Range	66–92	67–90
Place of birth		
Israel	15	12
Europe	12	17
North Africa/Middle East	6	2
Asia	2	0
CIS/Russia	1	1
South America	1	1
Years of education	13.51 (3.5)	14.08 (3.17)
Range	4–23	5–20
Marital status		
Single	3	5
Married	6	5
Divorced or separated	5	4
Widow/er	25	21
No. of children	2.16 (1.14)	1.64 (1.11)
Range	0–4	0–3
Cognitive Function		
MMSE	27.74 (1.88)	27.88 (2.05)
Range	23–30	22–30
Health		
No. of medical diagnoses	2.82 (1.6)	2.63 (1.5)
Range	0–7	0–7
Subjective health	2.36 (.81)	2.24 (.78)
Range	1–4	1–4
Participation in the I-SOCIAL		
No. of group intervention meetings attended	3.92 (2.15)	
Range	0–7	
No. of personal intervention meetings attended	5.77 (2.42)	
Range	1–13	

Statistical analysis showed no-significant differences between intervention and control groups in regards to demographic and background data.

concurrent results of both post-intervention and follow-up assessments and include all randomized participants, we utilized the mixed model (linear) procedure in SPSS with data from all 89 randomized participants and examined the interaction effect of time (baseline, post-intervention, and follow-up) by group (intervention vs control).

Effect size was calculated as:

$$\frac{(IG_t - IG_b) - (CG_t - CG_b)}{\text{Standard deviation of } (CG_t - CG_b)}$$

where IG = Intervention Group; CG = Control Group; t = after intervention or follow-up assessment; b = baseline assessment. In order to clarify the impact of the components of the intervention, we conducted a stepwise multiple regression with loneliness (separately for post-intervention and follow-up) as the dependent variable, and with the following independent variables: level of loneliness at baseline, number of individual meetings, and number of group sessions the participant partook of. Statistical analyses were performed using SPSS software (IBM, Armonk, NY).

3. Results

Participants were randomized into two groups (intervention and control). Statistically significant differences were not found between the groups with regard to demographics, health, and cognitive function (Table 1).

Intervention utilization. On average, participants were involved in 5.77 (SD = 2.42) individual meetings and attended 3.92 (SD = 2.15) group sessions with the majority choosing a combination of both. These numbers mask a large variability in involvement which is displayed in Table 2. One person participated in no meetings, while the largest subgroup (13 participants) had 5-7 individual meetings and attended 5–7 group sessions. Reasons for not attending varied greatly, from medical emergencies to lack of interest and various external barriers.

Table 2
Level of participation in individual and group sessions in the intervention group.

	Number of group sessions attended				
	0	1–2	3–4	5–7	Total
Number of individual meetings					
0	1	0	0	0	1
1–2	0	2	0	2	4
3–4	0	2	2	2	6
5–7	1	3	6	13	23
8–13	2	1	0	2	5
Total	4	8	8	19	39

Impact of the intervention on loneliness rates. The intervention group showed a significant decline in loneliness as compared to the control group both after the intervention and after the follow-up period. This difference yielded significant interaction terms in both ANOVAs ($p < .05$, Table 3, Fig. 2). The mixed model also revealed a significant effect for the interaction of intervention group by time, with an $F_{5,154.8} = 2.52$, $p < .05$. The effect size was 0.29 post-intervention and 0.24 at follow-up.

We used an 'intent to treat' analysis and included a participant who did not receive any intervention sessions. Our intent was to provide each participant with about seven individualized meetings and seven group sessions. When considering seven sessions of any kind as a minimal treatment threshold, 85% of the intervention group received this amount, and the effect size for this subgroup was .34 at post-intervention evaluation.

Reasons for not receiving the full-intended intervention were health problems either of spouses or of the participants themselves (e.g., a participant who was hospitalized in an intensive care unit during the intervention period and thus could not complete the process, and other participants who received chemotherapy) and lack of time due to a full-time job.

Predictors of post-intervention score. The regressions explaining loneliness score at post-intervention and follow-up by loneliness at baseline, number of individual meetings received, and number of group sessions attended are displayed in Table 4. Results were very similar for both regression analyses, i.e., baseline loneliness scores and number of group sessions attended were significant predictors of the final loneliness score, explaining 40.2% and 54.5% of their variances, respectively. Number of individual meetings attended did not emerge as a significant predictor.

Table 3
Changes in loneliness by time and by group (Control, Intervention). Results of two-way repeated measures ANOVAs.

Intervention group Mean (SD)		Control Group Mean (SD)		Interaction F Value
Baseline	Intervention	Baseline	Intervention	
Baseline vs. post-intervention				
N = 39		N = 35		
3.08 (.73)	2.81 (.74)	2.94 (.98)	3.06 (.89)	$F_{(1,72)} = 4.947$, $p < .05$
Baseline vs. follow-up				
N = 35		N = 28		
3.05 (.74)	2.72 (.67)	2.92 (1.05)	2.92 (.88)	$F_{(1,61)} = 4.379$, $p < .05$

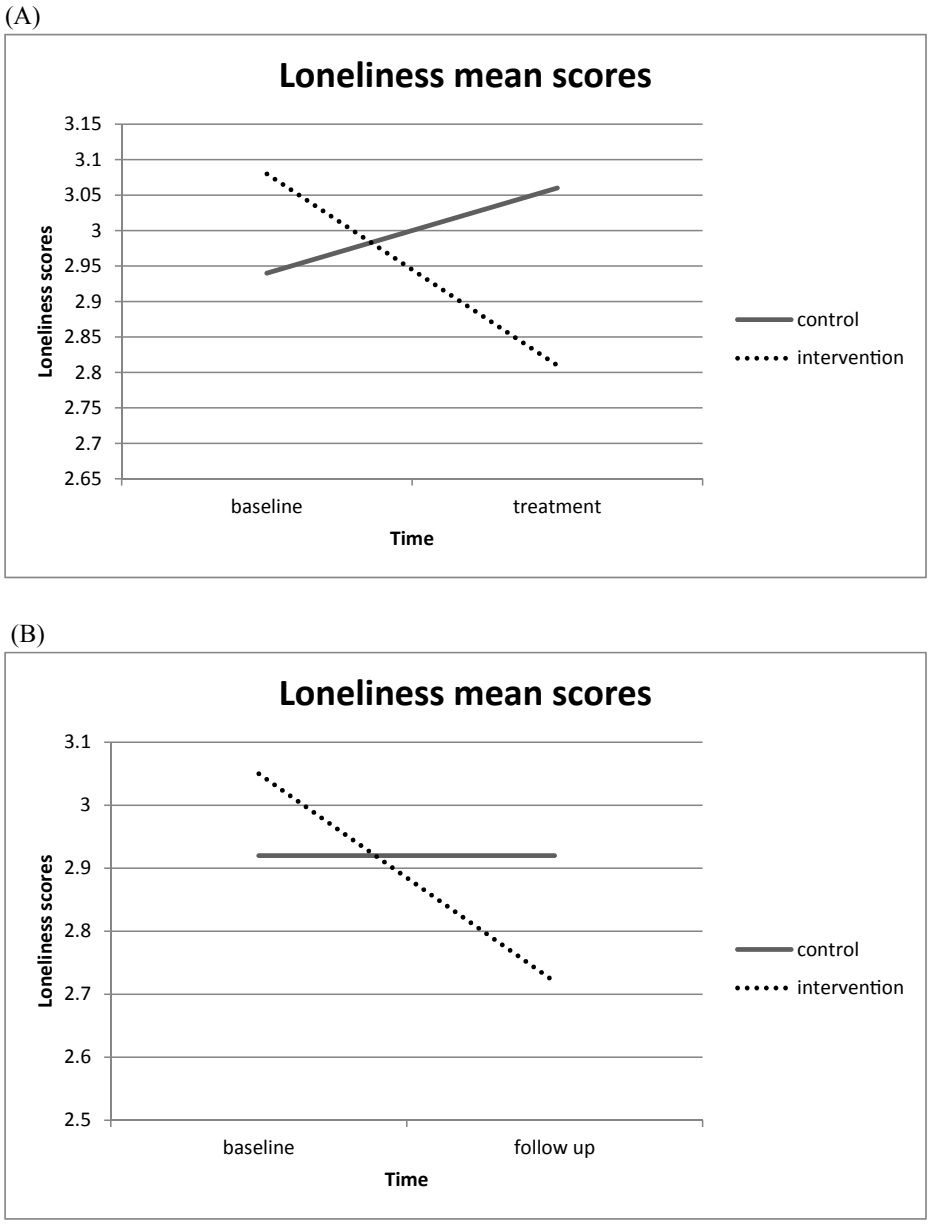

Fig. 2. Change in loneliness in the intervention vs. the control group (A) from baseline to end of intervention (n = 74) and (B) from baseline to end of follow-up. (n = 63).

Table 4
Stepwise regression analyses: explaining loneliness levels post-intervention and after follow-up with independent variables: baseline loneliness level, number of group sessions, and number of individual meetings.

	Mean loneliness level at post-intervention R^2 = 40.2%			Mean loneliness level at follow up R^2 = 54.5%		
	B	SE B	β	B	SE B	β
Mean of loneliness level at baseline	.58	.09	.60***	.63	.08	.72**
Number of group sessions	-.08	.04	-.25*	-.06	.03	-.21*

Number of individual meetings did not enter any of the regressions.
*$p < .05$ ***$p < .001$.

4. Discussion

This study found that the I-SOCIAL intervention for lonely older persons decreased loneliness significantly as compared with a no treatment control group. This finding is important for both substantive and methodological reasons. First, loneliness has been associated with multiple adverse effects, including risk of cognitive decline and dementia (Holwerda et al., 2014), mortality, and morbidity (Holt-Lunstad et al., 2015; Luo et al., 2012). Therefore, identifying interventions that decrease loneliness is crucial. Furthermore, prior intervention studies generally had either significant methodological problems or reached inconclusive results (Cohen-Mansfield and Perach, 2015), making this controlled trial an important step forward.

The study is pioneering in its individualization of treatment options to the needs of the participants, as it is the first study that combines individual and group intervention options, and it allows the participants to choose based on what is acceptable to them. Some lonely persons are not ready to participate in groups, which are perceived as too threatening, and individual meetings can ease the way towards this or towards another social activity. For others, individual meetings provide a less meaningful or potent intervention than groups, and these persons chose to participate only in groups, yet most participated in both. In addition to this format allowing a tailored intervention, individual meetings were further individualized by exploring the participant's barriers to social integration and examining, together with the

counselor, avenues to address these barriers. The intervention also involved counselors examining options for social activities in the participant's neighborhood and exploring their suitability for the participant. Thus, the intervention aimed to facilitate utilization of local resources that participants could make use of after the termination of the study.

The intervention resulted in a statistically significant reduction in loneliness rates in the intervention group with no such decline in the control group. Yet, the effect size obtained (0.29) is modest. Multiple reasons may be responsible for this, and their investigation should provide directions for future similar studies. First, we designed the intervention to be short based on several considerations. We thought that a short and therefore less expensive intervention would be more likely to be utilized by organizations that would target loneliness as an indicator for intervention, such as senior centers, HMOs, or community centers. In retrospect, we realize that the intervention period was too short. This was a complaint voiced by most participants, but we did not have the resources to lengthen the intervention period. Participants told us that they were just starting to try new social interactions at the end of the trial, and that they still needed and wanted additional support. We recommend that future studies using the I-SOCIAL present the intervention over longer periods.

The regression analysis revealed that the number of group sessions attended predicted the decrease in loneliness rates after the intervention. This finding likely reflects the crucial role of group sessions for modeling and practicing social skills, for developing connections with people who are seeking to develop new social ties, and for gaining insight into opportunities to enhance one's social network. However, it may also reflect the fact that those who attended group sessions were more ready – physically and socially – to enhance their social activities. Indeed, one of the goals of the individual meetings was to help those who were reluctant to attend groups overcome their barriers. Therefore, the statistically significant role of group attendance probably reflects both the impact of the groups but also the fact that group attendance was already an indicator of better readiness to tackle one's loneliness. In a similar vein, the number of individual meetings was not predictive of improvement in loneliness, as it was a reflection of different underlying processes. In some instances, a high number of individual meetings was indicative of more support needed to make progress, while a low number of meetings could mean that participants felt they were gaining from the group activities and therefore did not need the individual meetings. It could also include participants who gave up on the process.

Another insight for future work in this area pertains to available local resources. We assumed that we could rely on local social resources where participants would find avenues for continuing social activities. However, information received from participants, as well as that obtained by us directly, revealed a combination of insufficient, unsuitable, and non-accessible social opportunities in the community. In the senior centers, most of the activities tended to provide entertainment that required passive participation, such as listening to a concert or a lecture. Activities did not promote social interaction among attendees. This is a major failure of services for older persons, which needs to be addressed by those running the services, such as the local municipality. In addition, the social service system was not designed to address financial and mobility barriers. Indeed, a substantial proportion of the participants was poor, which is in line with research findings regarding the relationship between loneliness and low financial resources. Therefore, many could not afford to attend the local senior centers or similar activity opportunities. Others either had serious mobility limitations, could not use public transportation, or could not afford taxis. Our sample included persons with multiple physical, medical, financial, and personality limitations who were not provided with the needed support.

The sample was comprised of about 80% women. This is likely because there are more women in older populations, and women tend to be more lonely in old age (Cohen-Mansfield et al., 2016) for multiple reasons. They are less likely than men to be married and are often of lower economic status. Similarly, in our study, 57% of the men were married or living with a partner as compared to 9% of the women.

Cognitive function affects loneliness in multiple ways. When memory abilities deteriorate people are often avoided by their friends, contributing to loneliness. Furthermore, the impairment in both memory and organizational skills that is associated with Mild Cognitive Impairment (MCI) and with dementia is a barrier to initiation and development of new social contacts. Thus, cognitive status may impact participants' ability to benefit from the intervention. Whereas this study assessed cognitive function with the MMSE, future studies may further examine this issue by adding a diagnosis of MCI and dementia to the background assessment.

Within this study, we monitored verbal responses of the participants in both the group and the individual meetings. We intend to analyze these materials qualitatively, and we anticipate this analysis should shed more light on remaining issues concerning the intervention, such as how participants perceived encouragement to try activities or how to handle conflicts between group members. It should also highlight specific wishes and needs of group members, such as socialization in the evenings when participants are alone at home and afraid to go outdoors, or activities geared for specific subgroups, such as older men who are looking for a men's club type of venue. In addition to presenting the I-SOCIAL intervention for longer periods, future studies should develop the I-SOCIAL together with a local social agency that runs activities for older persons and that is ready to enhance the sociability impact of its current activities. Such a combined intervention may allow the I-SOCIAL or parts thereof to be offered on an indefinite basis.

The above limitations notwithstanding, this study is the first to utilize a well-designed trial to show the efficacy of a new, person-tailored, approach to decreasing loneliness among older persons. The results support conclusions from a review of loneliness interventions, which noted the relative effectiveness of educational programs that include guided social participation and the enhancement of participants' social networks (Cohen-Mansfield and Perach, 2015). The findings highlight the need for a change in approach to the prevention of loneliness in older persons and provide guidance for conducting new trials, which would optimize the I-SOCIAL approach to address this crucial social problem.

Potential conflicts of interest

The authors report no financial or other relationship relevant to the subject of this article.

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