Original Paper

An Entertainment-Education Video and Written Messages to Alleviate Loneliness in Germany: Pilot Randomized Controlled Study

Shuyan Liu¹, MSc, PhD; Luisa Wegner¹, BSc; Matthias Haucke¹, MSc, PhD; Jennifer Gates^{2,3}, BA; Maya Adam^{4,5}, BA, MD; Till Bärnighausen^{4,6,7}, MSc, MD, SCD

³Icahn School of Medicine, New York City, NY, United States

⁴Heidelberg Institute of Global Health, Heidelberg, Germany

⁵Department of Pediatrics, Stanford University School of Medicine, Stanford, CA, United States

⁶Africa Health Research Institute, Somkhele and Durban, South Africa

⁷Harvard Center for Population and Development Studies, Cambridge, MA, United States

Corresponding Author:

Till Bärnighausen, MSc, MD, SCD Heidelberg Institute of Global Health Im Neuenheimer Feld 130.3 Heidelberg, 69120 Germany Phone: 49 622156534 Fax: 49 622156594 Email: till.baernighausen@uni-heidelberg.de

Abstract

Background: More than half of adults in Germany have felt lonely during the COVID-19 pandemic. Previous studies highlight the importance of boosting positive emotions and social connectedness to combat loneliness. However, interventions targeting these protective psychosocial resources remain largely untested.

Objective: In this study, we aim to test the feasibility of a short animated storytelling video, written messages boosting social connectedness, and a combination of both for alleviating loneliness.

Methods: We enrolled 252 participants who were 18 years or older and spoke fluent German. Participants were recruited from a previous study on loneliness in Germany. We measured the effects of a combination of an animated video and written messages (intervention A), an animated video (intervention B), and written messages (intervention C) on loneliness, self-esteem, self-efficacy, and hope. We compared these with a control arm, which did not receive any intervention. The animated video was developed by Stanford University School of Medicine to reflect experiences of social isolation during the COVID-19 pandemic and convey messages of hope and solidarity. The written messages communicate four findings from recent studies on loneliness in Germany: (1) over a period of 6 months, 66% of respondents in Germany reported feeling lonely (feelings of loneliness are surprisingly common); (2) physical activity can ease feelings of loneliness; (3) focusing on "what really matters" in one's life can help to ease feelings of loneliness; and (4) turning to friends for companionship and support can ease feelings of loneliness. Participants were randomized 1:1:1:1 to interventions A, B, C, and the control condition, using the randomization feature of the web-based platform "Unipark," on which our trial takes place. Both the study investigators and analysts were blinded to the trial assignments. The primary outcome, loneliness, was measured using the short-form UCLA Loneliness Scale (ULS-8). Our secondary outcomes included the scores of the Coping with Loneliness Questionnaire, the 10-item Rosenberg Self-Esteem Scale (RSE), the 10-item General Self-Efficacy Scale, and the 12-item Adult Hope Scale (AHS).

Results: We observed no statistically significant effect of the tested interventions on loneliness scores, controlling for the baseline loneliness score before an intervention (all *P* values >.11). However, we observed significantly greater intention to cope with loneliness after exposure to an animated video when compared with the control (β =4.14; t_{248} =1.74; 1-tailed *P*=.04).

¹Department of Psychiatry and Psychotherapy (Campus Charité Mitte), Charité – Universitätsmedizin Berlin, Berlin, Germany

²Columbia University Mailman School of Public Health, New York City, NY, United States

Conclusions: Our results provide meaningful evidence for the feasibility of a full-scale study. Our study sheds light on the intention to cope with loneliness and explores the potential for creative digital interventions to enhance this psychological precursor, which is integral to overcoming loneliness.

Trial Registration: German Clinical Trials Register DRKS00027116; https://drks.de/search/en/trial/DRKS00027116

(JMIR Form Res 2023;7:e43036) doi: 10.2196/43036

KEYWORDS

entertainment media; perceived social isolation; health communication; digital knowledge

Introduction

Loneliness raises pressing public health concerns worldwide. The associated adverse effects on mental and physical health can shorten life [1], reduce social functioning (eg, social cohesion, trust, and participation) [2], and incur economic costs (eg, lost workdays and productivity, excess health and social care expenses) [3,4]. Moreover, loneliness appears to exhibit elements of contagion, spreading from person to person within social networks, suggesting that nonlonely individuals who are around lonely individuals tend to grow lonelier over time [5]. During the global COVID-19 pandemic, the public health community has focused special attention on the emerging "loneliness epidemic" [6-8].

More than 1 in 3 people in the United States, including 61% of young adults, faced "serious loneliness" during the COVID-19 pandemic [9]. In Europe, feelings of loneliness among EU residents doubled from 12% in 2016 to 25% in Spring 2020 [10]. In Germany, after the first lockdown in 2020, 66% of respondents reported feeling lonely [11]. Meanwhile, loneliness increased negative mood states including fatigue, anxiety, stress, depression, and unhappiness [12], and was associated with an increase in psychological distress over the first 12 months of the pandemic [13] and an increase in physiological stress during lockdown [14]. In the face of a potential "loneliness epidemic," innovative interventions and associated research on their efficacy are needed to provide convenient, scalable, and cost-effective methods for tackling loneliness [15,16].

The mechanisms underlying loneliness are not well-understood [1,17]. Loneliness is often associated with lower self-esteem and self-efficacy, negative affect, lower levels of hope, and limited use of coping strategies [1,17-19]. Interventions targeting loneliness often focus on 4 key aspects: changing cognitions (the strategy supported by the most convincing body of evidence), training social skills and participating in psychoeducation, supporting socialization or having a "socially focused supporter," and engaging with the "wider community" [20,21]. One potential strategy for addressing those 4 aspects and combating loneliness is to embed prosocial and health messages in entertainment media, well-known as entertainment-education (EE) [22,23].

Early EE initiatives drew insights from a wide range of theories [22,24,25], such as social cognitive theory [26], the theory of planned behavior (TPB) [27], the health belief model [28], belief system theory [29], and the elaboration likelihood model [30,31]. The dominant theoretical basis has been Bandura's [26] social cognitive theory, which suggests that EE encourages

https://formative.jmir.org/2023/1/e43036

Bandura [32], an observer exposed to entertainment media (eg, animated videos) obtains values and standards through imitation of others' behavior [33]. Thus, what is displayed in entertainment media influences the observers' understanding of an issue or phenomenon that occurs around them [32,33]. Motivation and perceived self-efficacy for imitating modeled behaviors are proportional to viewers' wishful identification and perceived similarity with the characters depicted in the EE [25,32]. In addition to Bandura's [26] social cognitive theory, the TPB suggests that behaviors are influenced by intentions [27]. The change in behavioral intentions reflects 3 types of characters from which observers can learn [34]: positive characters who support a prosocial value, negative characters who reject this value, and transitional characters who change from negative to positive characters over the course of the serial. As such, effective EE is designed to incorporate: (1) appealing storylines, (2) high-quality production, (3) unobtrusive persuasive messages, and (4) high potential for involvement with the characters [35,36]. Despite the rapid growth of EE, studies aimed at measuring its effects have been criticized for lacking rigor [34]. Thus, questions regarding the processes motivating potential behavior change are often left unanswered. This gap suggests a need for controlled experiments using EE content to better understand the theoretical mechanisms through which such content changes attitudes, feelings, and behaviors [25,30]. In this context, EE may change our attitudes toward loneliness (eg, is loneliness harmful to our health?), subjective norms (eg, is loneliness a common experience?), and perceived behavioral control (eg, can I take action against loneliness?), which stimulate the intention to cope with loneliness.

observational learning and behavioral modeling. According to

In addition to EE, previous studies have emphasized the importance of using research evidence to promote public health [37]. Indeed, health behavior change interventions are often criticized for lacking a research evidence base [38]. Evidence-based health messages created by researchers can raise awareness and reinforce behavioral change [39].

In our study, we aim to test the feasibility of an animated video, written message, or a combination of both for alleviating loneliness. We hypothesize that combining animated videos with written messages will be a creative, innovative, and feasible approach to tackling loneliness. This combined approach could help individuals alleviate loneliness, improve their intentions to cope with loneliness, increase levels of hope, improve their self-esteem and self-efficacy, and enhance their emotional state.

Methods

Participants and Procedure

We conducted a pilot randomized controlled web-based trial in Germany from December 2021 to February 2022 by using the web-based platform Unipark [40]. We enrolled participants who were 18 years or older and spoke fluent German. For recruitment, we contacted 881 participants in a previous study on loneliness in Germany. All participants had consented to be contacted for a future study. They were residents of Germany's 16 federal states and worked in various fields, such as office administration, health care, education, civil service, sales, agriculture, the arts, sports, and media.

Ethics Approval

The study was approved by the Ethics Committee of Charité–Universitätsmedizin Berlin (ethics number: EA2/143/20), was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and was registered on the German Clinical Trials Register [41] on November 24, 2021, with registration number #DRKS00027116. We followed Recommendations for Interventional Trials [42] and Good Clinical Practice guidelines [43]. Participants gave informed consent and received €10 (US \$10.90) compensation for their participation.

Study Intervention

Each participant was exposed to the intervention only once. We measured the effects of a combination of an animated video and written messages (intervention A, 4 minutes long), an animated video (intervention B, 3 minutes long), and written messages (intervention C, 1 minute long), and compared these with a control arm, which did not receive any intervention. The animated video was developed by Stanford University School of Medicine and can be viewed on YouTube [44]. The video did not contain any written or spoken language, and the written messages were written in German. Participants were randomized 1:1:1:1 to interventions A, B, C, and the control condition, using the randomization feature of the web-based Unipark platform on which our trial takes place. Participants in intervention group A watched the video first and then immediately read the message after watching the video. The written message conveyed 4 scientific facts without sound or animation.

The wordless animated video features an emotion-driven story-based portrayal of common experiences living through the COVID-19 pandemic. The narrative begins with people living inside socially isolated bubbles due to COVID-19. Their normal social interactions have been disrupted. The bubbles disappear when the COVID-19 vaccine arrives, allowing children to play together and families to gather. In addition to promoting vaccine confidence, the video is designed to reflect perceptions and experiences of social distancing and social isolation during the COVID-19 pandemic and convey messages of hope and solidarity.

The written messages communicated four findings from recent studies on loneliness in Germany. First, over a period of 6 months, 66% of respondents in Germany reported feeling lonely [11]. Feelings of loneliness are surprisingly common. Second,

```
https://formative.jmir.org/2023/1/e43036
```

physical movement can ease feelings of loneliness [45]. Third, focusing on "what really matters" in one's life could help to ease feelings of loneliness [46]. Fourth, turning to friends for companionship and support can ease feelings of loneliness [46].

Outcomes

We assessed participants' sociodemographic characteristics (ie, age, gender, years of education, and annual net income) and vaccination status. Our primary outcome was the sum score of the short-form UCLA Loneliness Scale (ULS-8) [47]. The detailed items of the ULS-8 questionnaire can be found in our previous study [11,13]. ULS-8, composed of 8 items, was rated on a 4-point Likert scale (1-4 points), with a total score ranging from 8 to 32, with higher scores indicating a higher level of loneliness. Our secondary outcomes included the mean score of the intention to cope with loneliness and each sum score of hope, self-esteem, and self-efficacy, which were measured by using 10 items from the Coping with Loneliness Questionnaire [48], the 12-item Adult Hope Scale (AHS) [49], the 10-item Rosenberg Self-Esteem Scale (RSE) [50], and the 10-item General Self-Efficacy Scale (GSES) [51], respectively. The intention to cope with loneliness was rated on a visual analog scale (range from 0 to 100), with higher scores indicating a higher intention to cope with loneliness. AHS was rated on an 8-point Likert scale (1-8 points) with a total score ranging from 12 to 96, with higher scores indicating higher hope. RSE and GSES were evaluated on a 4-point Likert scale (1-4 points) with a total score ranging from 10 to 40 and higher scores indicating higher self-esteem and self-efficacy, respectively. The scales that we used in our study were standard scales that have been validated and shown to be reliable in a German context [46,52-55].

To perform a manipulation check (ie, an attention check), we set up content-based questions geared toward identifying whether participants had paid attention to each intervention to which they were exposed. It consisted of 8 quiz questions in intervention A, 4 questions in intervention B, and 4 questions in intervention C. We excluded inattentive participants, who answered less than 50% of the questions correctly, from the analysis.

To measure emotional responses to the stimuli, we asked participants to rate valence or pleasantness, arousal or excitement [56], and loneliness or coping relevance for both the animated video and written messages by using the horizontal visual analog scale ranging from 0 (not at all) to 100 (very much).

The primary outcome was measured immediately before and after interventions, and the secondary outcome was only measured immediately after interventions. Participants' emotional responses to the stimuli, sociodemographic characteristics, and vaccination status were assessed at the end of the study.

Sample Size and Power Considerations

As the purpose of our pilot study was to assess the feasibility of the animated video and written messages to alleviate loneliness, we did not perform a power calculation. Our sample

XSL•FO RenderX

size was at least 50 participants per arm, which would be sufficient to evaluate the study design feasibility [57-60].

Data Analysis

We performed statistical analyses in R version 4.1.0 (R Foundation for Statistical Computing). To test whether loneliness scores decreased after an intervention, we built up a multiple regression model by using "4 trial arms" as the independent variable and "loneliness scores after an intervention" as the outcome while controlling for loneliness scores before an intervention. As recommended by Senn [61], we included loneliness scores before an intervention as a covariate to adjust the results for potential differences at baseline levels of loneliness. We used dummy coding for 4 trial arms to compare each intervention arm to the control arm as a reference. In addition, we added the covariates, including the intention to cope with loneliness, hope, self-esteem, self-efficacy, age, gender, years of education, and income. We then performed Bonferroni-adjusted significance tests for pairwise comparisons. Secondary outcomes were analyzed by building 4 separate linear models with the independent variable "trial arm" as a factor (the control arm as a contrast reference) and each secondary outcome as a dependent variable. To meet the assumption of having no multicollinearity in multiple regression, we calculated the variance inflation factor values for all independent variables. To compare participants' emotional responses to the animated video and written messages, we performed independent t tests. We compared differences in scores of valence or pleasantness, arousal or excitement, and loneliness or coping relevance between the animated video and written messages, for which 2-tailed P values were assumed.

Results

Overview

Among 881 participants, a total of 275 participants responded to us, and 23 participants did not want to participate in our study. Our final sample consists of 252 participants (184 females; age range 18-71, mean 33.93, SD 11.84 years) who completed our study. Table 1 shows the demographics of the participants in each group. Of the participants, 91.3% (n=230) were fully vaccinated against COVID-19. Each group had similar vaccination rates, which were aligned with similar attitudes toward COVID-19 vaccines. The mean ULS-8 loneliness scores before and after an intervention were 16.45 and 16.15 (ranging from 8 to 32), respectively.



Table 1. Sample characteristics.

Variable	Video and message (n=63)	Video (n=61)	Message (n=64)	Control (n=64)
Age (years), mean (SD)	34.03 (12.32)	33.93 (11.72)	34.44 (12.22)	33.33 (11.34)
Gender, n (%)				
Woman	47 (75)	43 (70)	46 (72)	48 (75)
Man	14 (22)	18 (30)	18 (28)	15 (23)
Other	2 (3)	0 (0)	0 (0)	1 (2)
Education years, mean (SD)	15.73 (4.06)	15.52 (3.6)	16.42 (5.58)	15.94 (3.77)
Income category, mean (SD) ^a	3.5 (1.69)	3.6 (1.98)	3.3 (1.61)	3.6 (1.85)
Vaccinated, n (%)				
No	4 (6)	4 (7)	2 (3)	2 (3)
Once	1 (2)	4 (7)	0 (0)	2 (3)
Twice	21 (33)	18 (30)	21 (33)	18 (28)
>Twice	36 (57)	35 (57)	39 (61)	42 (66)
Not to say	1 (2)	0 (0)	2 (3)	0 (0)
ULS-8 ^b loneliness score before intervention, mean (SD)	16.3 (4.8)	17.1 (5.14)	16.5 (5.52)	15.9 (4.61)
ULS-8 loneliness score after intervention, mean (SD)	15.8 (5.04)	17.2 (5.26)	16.0 (5.74)	15.6 (4.85)
Intention to cope with loneliness score after intervention, mean (SD)	60.4 (13.7)	60.1 (12.8)	58.1 (12.1)	56.0 (14.5)
Hope score (AHS ^c) after intervention, mean (SD)	63.2 (8.31)	61.8 (7.47)	64.9 (8.67)	62.6 (6.89)
Self-esteem score (RSE ^d) after intervention, mean (SD)	30.1 (6.68)	29.8 (6.79)	29.9 (6.9)	28.7 (6.29)
Self-efficacy score (GSES ^e) after intervention, mean (SD)	28.6 (5.45)	27.8 (5.29)	29.2 (4.99)	27.7 (5.61)

^aAnnual net income based on 12 income categories: (1) ⊕-€4999, (2) €5000-€9999, (3) €0,000-€14,999, (4) €5,000-€4,999, (5) €5,000-€49,999, (6) €50,000-€74,999, (7) €75,000-€99,999, (8) €100,000-€124,999, (9) €125,000-€149,999, (10) €150,000-€174,999, (11) €175,000-€200,000, and (12) above €200,000 (a currency exchange rate of €1=US \$1.09 is applicable).

^bULS-8: UCLA Loneliness Scale.

^cAHS: Adult Hope Scale.

^dRSE: Rosenberg Self-Esteem Scale.

^eGSES: General Self-Efficacy Scale.

Manipulation Check

In the video and message intervention group, participants answered on average 6.71 (SD 0.55) out of 8 questions correctly. In the video intervention group, participants correctly answered on average 2.93 (SD 0.25) out of 4 questions. In the message intervention group, participants correctly answered on average 3.84 (SD 0.37) out of 4 questions. We excluded participants if they answered less than 50% of the questions correctly; this was not the case in any intervention group. Thus, we conclude that participants paid attention to the video and messages.

To determine the overall effectiveness of an intervention independent of the specific type of intervention, we conducted an independent-sample *t* test. Importantly, these results were not controlled for variation at baseline levels of loneliness within each trial arm and were not corrected for multiple testing. For each intervention, there was a statistically significant reduction in loneliness score after the intervention (mean 16.15, SD 5.24) compared to before the intervention (mean 16.45, SD 5.02; t_{251} =2.44; *P*=.02). The mean difference in loneliness score was 0.30 (95% CI 0.06-0.54).

```
https://formative.jmir.org/2023/1/e43036
```

To test for specific intervention effects, we conducted a multiple regression analysis. The regression analysis results are displayed in Table 2; all generalized variance inflation factors were <3. In comparison to the control, we did not find a significant effect of the interventions on the loneliness scores after an intervention by adding covariables, including controlling for baseline loneliness scores before an intervention (all P values >.11), as shown in Figure 1. However, the baseline loneliness score before an intervention had a significant impact on loneliness scores after an intervention (β =.93; t_{239} =29.58; P<.001). In addition, we found that self-esteem (β =-.065; t_{239} =-2.103; P=.04) and income (β =.229; t_{239} =2.902; P=.004) had a significant effect on loneliness scores after an intervention, reflecting higher self-esteem, and lower income was associated with a lower level of loneliness. As self-esteem and income were significantly associated with loneliness scores after an intervention, we conducted a 2-way ANOVA to compare the effects in each intervention group. We found that there was neither a statistically significant difference in self-esteem ($F_{3,248}$ =0.594; P=.62), nor income between the intervention groups $(F_{3,248}=0.346; P=.79).$

XSL•FO

To calculate effect sizes, we conducted a pairwise comparison of loneliness scores before and after an intervention. The respective effect sizes, *t* values, and *P* values are shown in Table 3. Based on Cohen's classification of effect sizes (d=0.2), medium (d=0.5), and large (d=0.8) [62], the observed effects are small. Interestingly, "Video and Message" versus "Video" (d=-0.319) and "Video" versus "Message" (d=0.263) had the highest difference in loneliness scores.

For secondary outcomes, we hypothesized that the animated video and written messages would increase intentions to cope with loneliness; therefore, we report 1-tailed P values. A linear model showed higher scores of coping with loneliness after

exposure to a combination of animated video and written messages (β =4.37; t_{248} =1.85; 1-tailed *P*=.03) and after watching the animated video (β =4.14; t_{248} =1.74; 1-tailed *P*=.04) as compared to the control, as shown in Figure 2, although the message did not increase intentions to cope with loneliness (β =2.1; t_{246} =0.89; 1-tailed *P*=.19).

Regarding participants' emotional responses to the animated video and written messages, we found higher valence/pleasantness (t_{249} =-2.66; P=.008), arousal or excitement (t_{249} =-2.33; P=.02), and coping relevance (t_{249} =-4.56; P<.001) to written messages as compared to the animated video, as shown in Figure 3.

Table 2. Results of the multiple regression analyses of the loneliness scores after an intervention as an outcome.

Variable	b	SE b	T value	P value
Video and message versus control	-0.096	0.342	-0.279	.78
Video versus control	0.558	0.349	1.600	.11
Message versus control	0.076	0.342	0.222	.82
Covariates				
Baseline loneliness scores before intervention	0.926	0.031	29.582	<.001
Intention to cope	0.003	0.011	0.275	.78
Норе	0.015	0.02	0.750	.45
Self-esteem	-0.065	0.031	-2.103	.04
Self-efficacy	-0.022	0.038	-0.570	.57
Age	0.002	0.012	0.130	.90
Gender	0.032	0.257	0.126	.90
Years of education	-0.026	0.028	-0.914	.36
Income	0.229	0.079	2.902	.004

Figure 1. The mean difference between loneliness scores as the primary outcome before and after intervention among the 4 trial arms. The 4 trial arms are a combination of an animated video and written messages, an animated video, and written messages against a control condition. There is no significance in the mean difference in loneliness scores between the 4 trial arms.



 Table 3. Effect sizes (Cohen d) for the difference in loneliness scores for each trial arm.

Trial arm	T test (df)	Bonferroni adjusted	Effect size
		P values	(Cohen d)
Video and message versus control	-0.68 (124)	>.99	-0.120
Video versus control	1.09 (120)	>.99	0.196
Message versus control	-0.33 (124)	>.99	-0.059
Video and message versus video	-1.77 (115)	.40	-0.319
Video and message versus message	-0.38 (125)	>.99	-0.067
Video versus message	1.46 (114)	.80	0.263

Figure 2. Secondary outcome after an intervention. The differential effects of a combination of animated video and written messages, an animated video, and written messages against a control condition on scores of coping with loneliness (A), hope (B), self-esteem (C), and self-efficacy (D). Significant at P (1-tailed test).





Figure 3. Emotional responses (pleasantness A and excitement B) and the relevance of coping with loneliness (C) to the animated video and written messages. Significant at ***P < .001 (2-tailed test).



Discussion

In this study, we proposed that combining story-based, animated video content with written messages may be a new and powerful way to convey technical concepts to nonspecialized audiences. However, we found that there was no significant difference in loneliness scores between specific intervention groups after controlling for baseline loneliness scores. Interestingly, we found that overall loneliness scores were lower after exposure to an intervention, regardless of the type of intervention selected. Moreover, we found higher scores on intention to cope with loneliness after exposure to the animated video when compared with the control.

EE videos may be more effective for improving individuals' intentions to cope with loneliness than reducing feelings of loneliness immediately following exposure. In accordance with the TPB, intentions to change are determined by 3 factors: attitudes, subjective norms, and perceived behavioral control [27]. In this context, there are 3 potential underlying reasons why the intention to deal with loneliness was changed by watching the EE videos. This change of intention may be caused by a change in attitudes toward loneliness, the subjective norm of being lonely, as well as one's perceived and actual behavioral control over loneliness. Beyond positive and negative characters

RenderX

in EE, transitional characters provide particularly relevant models from which observers can learn [34]. Observers may relate to the uncertainty and doubt transitional characters experience when first considering a new behavior and can observe the characters being rewarded for their adoption of the behavior as the story progresses [63]. A meta-analysis showed that a medium-to-large change in behavioral intentions (d=0.66) engenders a small-to-medium change in behavior (d=0.36) [64]. Together with previous studies, a digitally animated video can be a science education and communication resource for the general public, but it can also be a tool to improve public health by improving awareness and inspiring people to pursue knowledge [65,66].

In the context of pandemic-related challenges, such as social distancing and increased feelings of loneliness, digital interventions that can reach a broad audience in order to prevent or reduce social isolation and loneliness become even more important [67,68]. The use of short, wordless, and animated video content, designed for rapid dissemination of evidence-based health information, constitutes an innovative approach to supporting global, public responses to crises. [69]. Such interventions have the potential to inspire people to engage in collective action to address social problems [70,71].

Our pilot study played a foundational role in preparation for conducting a full-scale research study. Only 23 out of 275 participants did not want to participate in our study. All participants paid attention to our interventions. They rated the interventions as pleasant, with an average rating above 60 (ranging from 0-100). Effect sizes in our pilot study can be used to determine the sample size for future studies. Given the observed small effect size of the "trial arm," our power analysis indicated that the estimated sample size for a full-scale study would be 1492 participants. The intention to cope with loneliness was not a primary outcome but a secondary outcome in this study. A full-scale study may include it as a primary outcome and assess participants' intentions to cope with loneliness both before and after an intervention.

Study limitations include selection bias associated with the recruitment of participants from a previous study on loneliness in Germany. Therefore, any treatment effect of this pilot study may be blunted by this selection bias [72] and the inclusion of a high rate of female participants. The mixed methods

intervention design may have enriched the intervention evaluations. Moreover, the mean ULS-8 loneliness scores before and after an intervention were not very high, with 16.45 and 16.15 (ranging from 8 to 32), respectively. This may reflect that our participants had low levels of loneliness, which might have led to a "floor effect" [73]. Thus, it remains possible that our interventions might have high-level effects among participants who reported high levels of loneliness.

To conclude, we found that animated videos increased participants' intentions to cope with loneliness but did not decrease loneliness scores. Our novel approach lays the foundation for assessing to what extent the components of digital interventions to reduce loneliness are "transferable" to other settings (eg, in different countries) and whether they are likely to result in the same or similar impacts. An effective early intervention to tackle loneliness and social isolation amid COVID-19 and beyond will be key to both better health outcomes and lower health and social care costs in the long term.

Acknowledgments

We thank all the participants in our study. This study is supported by internal research funds from Charité–Universitätsmedizin Berlin (SL). For the publication fee, we acknowledge financial support by Deutsche Forschungsgemeinschaft within the funding programme "Open Access Publikationskosten" as well as by Heidelberg University.

Data Availability

Data are available with restrictions due to confidentiality in line with the Berlin Data Protection Act (Berliner Datenschutzgesetz, BlnDSG). Interested individuals can contact stresshealth@charite.de.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-eHEALTH checklist (V 1.6.1). [PDF File (Adobe PDF File), 445 KB-Multimedia Appendix 1]

References

- Hawkley LC, Cacioppo JT. Loneliness matters: a theoretical and empirical review of consequences and mechanisms. Ann Behav Med 2010;40(2):218-227 [FREE Full text] [doi: 10.1007/s12160-010-9210-8] [Medline: 20652462]
- Cassie KM, Miller-Cribbs J, Smith A. An exploratory study of factors associated with social isolation and loneliness in a community sample. Soc Work Health Care 2020;59(7):485-498 [FREE Full text] [doi: 10.1080/00981389.2020.1795780] [Medline: 32783600]
- Mihalopoulos C, Le LKD, Chatterton ML, Bucholc J, Holt-Lunstad J, Lim MH, et al. The economic costs of loneliness: a review of cost-of-illness and economic evaluation studies. Soc Psychiatry Psychiatr Epidemiol 2020;55(7):823-836 [FREE Full text] [doi: 10.1007/s00127-019-01733-7] [Medline: 31119308]
- McDaid D, Bauer A, Park AL. Making the economic case for investing in actions to prevent and/or tackle loneliness: a systematic review. London School of Economics and Political Science. 2017. URL: <u>https://www.lse.ac.uk/business/</u> <u>consulting/reports/making-the-economic-case-for-investing-in-actions-to-prevent-and-or-tackle-loneliness</u> [accessed 2023-05-13]
- 5. Cacioppo JT, Fowler JH, Christakis NA. Alone in the crowd: the structure and spread of loneliness in a large social network. J Pers Soc Psychol 2009;97(6):977-991 [FREE Full text] [doi: 10.1037/a0016076] [Medline: 19968414]
- 6. MacArthur KR. Treating loneliness in the aftermath of a pandemic: threat or opportunity? In: Ryan JM, editor. COVID-19: Volume I: Global Pandemic, Societal Responses, Ideological Solutions. Oxfordshire, England, UK: Routledge; 2020:197-208
- Varga TV, Bu F, Dissing AS, Elsenburg LK, Bustamante JJH, Matta J, et al. Loneliness, worries, anxiety, and precautionary behaviours in response to the COVID-19 pandemic: a longitudinal analysis of 200,000 Western and Northern Europeans. Lancet Reg Health Eur 2021;2:100020 [FREE Full text] [doi: 10.1016/j.lanepe.2020.100020] [Medline: <u>33870246</u>]

- Liu S, Heinz A, Haucke MN, Heinzel S. Globale auswirkungen der COVID-19-pandemie auf die versorgung von menschen mit psychischen erkrankungen. Nervenarzt 2021;92(6):556-561 [FREE Full text] [doi: 10.1007/s00115-021-01068-2] [Medline: 33575836]
- 9. Weissbourd R, Batanova M, Lovison V, Torres E. Loneliness in America: how the pandemic has deepened an epidemic of loneliness and what we can do about it. Harvard Graduate School of Education. 2021. URL: <u>https://tinyurl.com/mwd5z5u5</u> [accessed 2023-05-13]
- 10. Baarck J, Balahur-Dobrescu A, Cassio LG, D'Hombres B, Pasztor Z, Tintori G. Loneliness in the EU. Insights from surveys and online media data. European Commission. 2021. URL: <u>https://publications.jrc.ec.europa.eu/repository/handle/JRC125873</u> [accessed 2023-05-13]
- Liu S, Heinzel S, Haucke MN, Heinz A. Increased psychological distress, loneliness, and unemployment in the spread of COVID-19 over 6 months in Germany. Medicina (Kaunas) 2021;57(1):53 [FREE Full text] [doi: 10.3390/medicina57010053] [Medline: 33435368]
- Haucke M, Liu S, Heinzel S. The persistence of the impact of COVID-19–related distress, mood inertia, and loneliness on mental health during a postlockdown period in Germany: an ecological momentary assessment study. JMIR Ment Health 2021;8(8):e29419 [FREE Full text] [doi: 10.2196/29419] [Medline: 34347622]
- 13. Liu S, Haucke MN, Heinzel S, Heinz A. Long-term impact of economic downturn and loneliness on psychological distress: triple crises of COVID-19 pandemic. J Clin Med 2021;10(19):4596 [FREE Full text] [doi: 10.3390/jcm10194596] [Medline: 34640614]
- Haucke M, Golde S, Saft S, Hellweg R, Liu S, Heinzel S. The effects of momentary loneliness and COVID-19 stressors on hypothalamic-pituitary adrenal (HPA) axis functioning: a lockdown stage changes the association between loneliness and salivary cortisol. Psychoneuroendocrinology 2022;145:105894 [FREE Full text] [doi: 10.1016/j.psyneuen.2022.105894] [Medline: 36007471]
- Williams CYK, Townson AT, Kapur M, Ferreira AF, Nunn R, Galante J, et al. Interventions to reduce social isolation and loneliness during COVID-19 physical distancing measures: a rapid systematic review. PLoS One 2021;16(2):e0247139 [FREE Full text] [doi: 10.1371/journal.pone.0247139] [Medline: 33596273]
- 16. Brandt L, Liu S, Heim C, Heinz A. The effects of social isolation stress and discrimination on mental health. Transl Psychiatry 2022;12(1):398 [FREE Full text] [doi: 10.1038/s41398-022-02178-4] [Medline: 36130935]
- 17. Cacioppo JT, Cacioppo S, Boomsma DI. Evolutionary mechanisms for loneliness. Cogn Emot 2014;28(1):3-21 [FREE Full text] [doi: 10.1080/02699931.2013.837379] [Medline: 24067110]
- Bareket-Bojmel L, Shahar G, Abu-Kaf S, Margalit M. Perceived social support, loneliness, and hope during the COVID-19 pandemic: testing a mediating model in the UK, USA, and Israel. Br J Clin Psychol 2021;60(2):133-148 [FREE Full text] [doi: 10.1111/bjc.12285] [Medline: 33624294]
- 19. Teneva N, Lemay EP. Projecting loneliness into the past and future: implications for self-esteem and affect. Motiv Emot 2020;44(5):772-784 [FREE Full text] [doi: 10.1007/s11031-020-09842-6]
- 20. Mann F, Bone JK, Lloyd-Evans B, Frerichs J, Pinfold V, Ma R, et al. A life less lonely: the state of the art in interventions to reduce loneliness in people with mental health problems. Soc Psychiatr Epidemiol 2017;52(6):627-638 [FREE Full text] [doi: 10.1007/s00127-017-1392-y] [Medline: 28528389]
- Macià D, Cattaneo G, Solana J, Tormos JM, Pascual-Leone A, Bartrés-Faz D. Meaning in life: a major predictive factor for loneliness comparable to health status and social connectedness. Front Psychol 2021;12:627547 [FREE Full text] [doi: 10.3389/fpsyg.2021.627547] [Medline: <u>33716892</u>]
- 22. Singhal A, Rogers EM. A theoretical agenda for entertainment—education. Commun Theory 2002;12(2):117-135 [FREE Full text] [doi: 10.1111/j.1468-2885.2002.tb00262.x]
- 23. Sood S, Riley AH, Alarcon KC. Entertainment-education and health and risk messaging. In: Oxford Research Encyclopedia of Communication. Oxford, United Kingdom: Oxford University Press; 2017:1-51
- 24. Sood S, Menard T, Witte K. The theory behind entertainment-education. In: Singhal A, editor. Entertainment-Education and Social Change: History, Research, and Practice. Mahwah, NJ, US: Lawrence Erlbaum Associates Publishers; 2004:117-149
- 25. Moyer-Gusé E. Toward a theory of entertainment persuasion: explaining the persuasive effects of entertainment-education messages. Commun Theory 2008;18(3):407-425 [FREE Full text] [doi: 10.1111/j.1468-2885.2008.00328.x]
- 26. Bandura A. Social Foundations of Thought and Action: A Social Cognitive Theory. Englewood Cliffs, NJ: Prentice Hall; 1986.
- 27. Ajzen I. The theory of planned behavior. Organ Behav Hum Decis Process 1991;50(2):179-211 [FREE Full text] [doi: 10.1016/0749-5978(91)90020-t]
- 28. Becker MH, Rosenstock IM. Comparing social learning theory and the health belief model. In: Ward WB, editor. Advances in Health Education and Promotion. Amsterdam: Elsevier Science and Technology Books; 1987:245-249
- 29. Rokeach M. Beliefs, Attitudes, and Values: A Theory of Organization and Change. San Francisco: Jossey-Bass; 1968.
- 30. Slater MD, Rouner D. Entertainment-education and elaboration likelihood: understanding the processing of narrative persuasion. Commun Theory 2002;12(2):173-191 [FREE Full text] [doi: 10.1111/j.1468-2885.2002.tb00265.x]

- 31. Petty R, Cacioppo J. The elaboration likelihood model of persuasion. In: Communication and Persuasion. New York, NY: Springer; 1986:1-24
- 32. Bandura A. Social cognitive theory of mass communication. Media Psychology 2001;3(3):265-299 [FREE Full text] [doi: 10.1207/S1532785XMEP0303_03]
- Rasit RM, Hamjah SH, Tibek SR, Sham FM, Ashaari MF, Samsudin MA, et al. Educating film audience through social cognitive theory reciprocal model. Procedia Soc Behav Sci 2015;174:1234-1241 [FREE Full text] [doi: 10.1016/j.sbspro.2015.01.742]
- 34. Pajares F, Prestin A, Chen J, Nabi R. Social cognitive theory and media effects. In: Oliver MB, Nabi RL, editors. The SAGE Handbook of Media Processes and Effects. California: SAGE Publications; 2009:283-297
- Adam M, McMahon SA, Prober C, Bärnighausen T. Human-centered design of video-based health education: an iterative, collaborative, community-based approach. J Med Internet Res 2019;21(1):e12128 [FREE Full text] [doi: 10.2196/12128] [Medline: 30698531]
- 36. Prestin A. The pursuit of hopefulness: operationalizing hope in entertainment media narratives. Media Psychology 2013;16(3):318-346 [FREE Full text] [doi: 10.1080/15213269.2013.773494]
- Ginis KAM, Heisz J, Spence JC, Clark IB, Antflick J, Ardern CI, et al. Formulation of evidence-based messages to promote the use of physical activity to prevent and manage Alzheimer's disease. BMC Public Health 2017;17(1):209 [FREE Full text] [doi: 10.1186/s12889-017-4090-5] [Medline: 28212648]
- Green LW, Ottoson JM, García C, Hiatt RA. Diffusion theory and knowledge dissemination, utilization, and integration in public health. Annu Rev Public Health 2009;30:151-174 [FREE Full text] [doi: 10.1146/annurev.publhealth.031308.100049] [Medline: 19705558]
- Heath GW, Parra DC, Sarmiento OL, Andersen LB, Owen N, Goenka S, Lancet Physical Activity Series Working Group. Evidence-based intervention in physical activity: lessons from around the world. Lancet 2012;380(9838):272-281 [FREE Full text] [doi: 10.1016/S0140-6736(12)60816-2] [Medline: 22818939]
- 40. Online survey software: surveys made easy with unipark. Unipark. 2023. URL: <u>https://www.unipark.com/en/</u> [accessed 2023-05-13]
- 41. German Clinical Trials Register. 2023. URL: <u>https://www.bfarm.de/DE/Das-BfArM/Aufgaben/</u> Deutsches-Register-Klinischer-Studien/_node.html [accessed 2023-05-13]
- 42. Moher D, Chan AW. SPIRIT (standard protocol items: recommendations for interventional trials). In: Moher D, Altman D, Wager E, Simera I, Schulz K, editors. Guidelines for Reporting Health Research: A User's Manual. United Kingdom: Wiley; 2014:56-67
- 43. Guideline IHT. Guideline for good clinical practice. Postgrad Med J 2001;47(3):199-203 [FREE Full text]
- 44. Sealion video. YouTube. 2023. URL: https://youtu.be/YZn1-tBHBNs [accessed 2023-05-13]
- 45. Haucke M, Heinz A, Liu S, Heinzel S. The impact of COVID-19 lockdown on daily activities, cognitions, and stress in a lonely and distressed population: temporal dynamic network analysis. J Med Internet Res 2022;24(3):e32598 [FREE Full text] [doi: 10.2196/32598] [Medline: 35191843]
- Wegner L, Haucke MN, Heinzel S, Liu S. Smartphone-based ecological momentary assessment of coping with loneliness amid COVID-19 in Germany. Int J Environ Res Public Health 2022;19(7):3946 [FREE Full text] [doi: 10.3390/ijerph19073946] [Medline: 35409629]
- 47. Hays RD, DiMatteo MR. A short-form measure of loneliness. J Pers Assess 1987;51(1):69-81 [FREE Full text] [doi: 10.1207/s15327752jpa5101_6] [Medline: 3572711]
- 48. Rokach A, Brock H. Coping with loneliness. J Psychol 1998;132(1):107-127 [FREE Full text] [doi: 10.1080/00223989809599269]
- 49. Snyder CR, Harris C, Anderson JR, Holleran SA, Irving LM, Sigmon ST, et al. The will and the ways: development and validation of an individual-differences measure of hope. J Pers Soc Psychol 1991;60(4):570-585 [FREE Full text] [doi: 10.1037//0022-3514.60.4.570] [Medline: 2037968]
- 50. Rosenberg M. Rosenberg self-esteem scale (RSE). APA PsycTests 1965;61(52):18 [FREE Full text] [doi: 10.1037/t01038-000]
- 51. Schwarzer R, Jerusalem M. Generalized self-efficacy scale. In: Weinman J, Johnston M, Wright SC, editors. Measures in Health Psychology A User's Portfolio—Causal and Control Beliefs. Windsor: NFER-NELSON; 1995:35-37
- 52. Liu S, Heinz A. Cross-cultural validity of psychological distress measurement during the coronavirus pandemic. Pharmacopsychiatry 2020;53(5):237-238 [FREE Full text] [doi: 10.1055/a-1190-5029] [Medline: 32583390]
- 53. Stoeber F, Reschke K. Erfassung und nutzung des hoffnungskonzeptes nach C. R. snyder im psychotherapeutischen kontext. Verhaltenstherapie und psychosoziale Praxis 2016;48(3):643-651
- 54. Ferring D, Filipp SH. Messung des Selbstwertgefühls: Befunde zu Reliabilität, Validität und Stabilität der Rosenberg-Skala. Diagnostica 1996;42:284-292 [FREE Full text]
- 55. Schwarzer R, Jerusalem M. Skalen zur erfassung von Lehrer-und schülermerkmalen. In: Dokumentation der psychometrischen Verfahren im Rahmen der Wissenschaftlichen Begleitung des Modellversuchs Selbstwirksame Schulen. Berlin: Freie Universität Berlin; 1999.
- 56. Bradley MM, Lang PJ. Measuring emotion: the self-assessment manikin and the semantic differential. J Behav Ther Exp Psychiatry 1994;25(1):49-59 [FREE Full text] [doi: 10.1016/0005-7916(94)90063-9] [Medline: 7962581]

- Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. J Psychiatr Res 2011;45(5):626-629 [FREE Full text] [doi: 10.1016/j.jpsychires.2010.10.008] [Medline: 21035130]
- 58. Funk LM, Breuer CR, Venkatesh M, Muraveva A, Alagoz E, Hanlon BM, et al. Protocol and short-term results for a feasibility randomized controlled trial of a video intervention for veterans with obesity: the TOTAL (Teaching Obesity Treatment Options to Adult Learners) pilot study. Contemp Clin Trials Commun 2021;23:100816 [FREE Full text] [doi: 10.1016/j.conctc.2021.100816] [Medline: 34258469]
- 59. Bell ML, Whitehead AL, Julious SA. Guidance for using pilot studies to inform the design of intervention trials with continuous outcomes. Clin Epidemiol 2018;10:153-157 [FREE Full text] [doi: 10.2147/CLEP.S146397] [Medline: 29403314]
- 60. Ampofo AG, Gyamfuaah SA, Opoku NS, Owusu SO, Ibitoye MB. A pilot study of a video-based educational intervention and knowledge of cervical cancer among senior high school students in Ghana: A before-after study. J Cancer Policy 2020 Jun;24(6):100220 [doi: 10.1016/j.jcpo.2020.100220]
- 61. Senn S. Change from baseline and analysis of covariance revisited. Stat Med 2006;25(24):4334-4344 [FREE Full text] [doi: 10.1002/sim.2682] [Medline: 16921578]
- 62. Cohen J. Am Psychologist 1995 Dec;50(12):1103-1103 [FREE Full text] [doi: 10.1037/0003-066X.50.12.1103]
- 63. Singhal A, Rogers E. Entertainment-Education: A Communication Strategy for Social Change. Mahwah, New Jersey: Routledge; 1999.
- 64. Webb TL, Sheeran P. Does changing behavioral intentions engender behavior change? A meta-analysis of the experimental evidence. Psychol Bull 2006;132(2):249-268 [FREE Full text] [doi: 10.1037/0033-2909.132.2.249] [Medline: 16536643]
- 65. Adam M, Chase RP, McMahon SA, Kuhnert KL, Johnston J, Ward V, et al. Design preferences for global scale: a mixed-methods study of "glocalization" of an animated, video-based health communication intervention. BMC Public Health 2021;21(1):1223 [FREE Full text] [doi: 10.1186/s12889-021-11043-w] [Medline: 34172016]
- Adam M, Bärnighausen T, McMahon SA. Design for extreme scalability: a wordless, globally scalable COVID-19 prevention animation for rapid public health communication. J Glob Health 2020;10(1):010343 [FREE Full text] [doi: 10.7189/jogh.10.010343] [Medline: 32411360]
- 67. Rodrigues NG, Han CQY, Su Y, Klainin-Yobas P, Wu XV. Psychological impacts and online interventions of social isolation amongst older adults during COVID-19 pandemic: a scoping review. J Adv Nurs 2022;78(3):609-644 [FREE Full text] [doi: 10.1111/jan.15063] [Medline: 34625997]
- 68. Banerjee D, Rai M. Social isolation in Covid-19: the impact of loneliness. Int J Soc Psychiatry 2020;66(6):525-527 [FREE Full text] [doi: 10.1177/0020764020922269] [Medline: 32349580]
- Vandormael A, Adam M, Greuel M, Gates J, Favaretti C, Hachaturyan V, et al. The effect of a wordless, animated, social media video intervention on COVID-19 prevention: online randomized controlled trial. JMIR Public Health Surveill 2021;7(7):e29060 [FREE Full text] [doi: 10.2196/29060] [Medline: 34174778]
- 70. Bonardi O, Wang Y, Li K, Jiang X, Krishnan A, He C, et al. Effects of COVID-19 mental health interventions among children, adolescents, and adults not quarantined or undergoing treatment due to COVID-19 infection: a systematic review of randomised controlled trials. Can J Psychiatry 2022;67(5):336-350 [FREE Full text] [doi: 10.1177/07067437211070648] [Medline: 35275494]
- Owoyemi A, Okolie EA, Omitiran K, Amaechi UA, Sodipo BO, Ajumobi O, et al. Importance of community-level interventions during the COVID-19 pandemic: lessons from Sub-Saharan Africa. Am J Trop Med Hyg 2021;105(4):879-883 [FREE Full text] [doi: 10.4269/ajtmh.20-1533] [Medline: 34370697]
- 72. Beets MW, Weaver RG, Ioannidis JPA, Geraci M, Brazendale K, Decker L, et al. Identification and evaluation of risk of generalizability biases in pilot versus efficacy/effectiveness trials: a systematic review and meta-analysis. Int J Behav Nutr Phys Act 2020;17(1):19 [FREE Full text] [doi: 10.1186/s12966-020-0918-y] [Medline: 32046735]
- 73. Lim CR, Harris K, Dawson J, Beard DJ, Fitzpatrick R, Price AJ. Floor and ceiling effects in the OHS: an analysis of the NHS PROMs data set. BMJ Open 2015;5(7):e007765 [FREE Full text] [doi: 10.1136/bmjopen-2015-007765] [Medline: 26216152]

Abbreviations

AHS: Adult Hope Scale
EE: entertainment-education
GSES: General Self-Efficacy Scale
RSE: Rosenberg Self-Esteem Scale
TPB: theory of planned behavior
ULS-8: UCLA Loneliness Scale



Edited by A Mavragani; submitted 28.09.22; peer-reviewed by SGS Shah, K Bredbenner, C Hao; comments to author 07.02.23; revised version received 28.02.23; accepted 30.04.23; published 07.06.23

<u>Please cite as:</u> Liu S, Wegner L, Haucke M, Gates J, Adam M, Bärnighausen T An Entertainment-Education Video and Written Messages to Alleviate Loneliness in Germany: Pilot Randomized Controlled Study JMIR Form Res 2023;7:e43036 URL: <u>https://formative.jmir.org/2023/1/e43036</u> doi: <u>10.2196/43036</u> PMID: <u>37285206</u>

©Shuyan Liu, Luisa Wegner, Matthias Haucke, Jennifer Gates, Maya Adam, Till Bärnighausen. Originally published in JMIR Formative Research (https://formative.jmir.org), 07.06.2023. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Formative Research, is properly cited. The complete bibliographic information, a link to the original publication on https://formative.jmir.org, as well as this copyright and license information must be included.

