Assessing the impact of Social Networking Site use on older people's loneliness and social isolation. A randomized controlled trial: The Aging in a Networked Society-Social Experiment Study (ANS-SE)

Daniele Zaccaria [a, *], Antonio Guaita [b], Roberta Vaccaro [b], Georgia Casanova [c], Simona Abbondanza [b], Laura Pettinato [d], Gabriele Cerati [b], Elena Rolandi [b], Emanuela Sala [d]

[a] University of Applied Sciences and Arts of Southern Switzerland, Department of Business Economics, Health and Social Care, Centre of Competence on Ageing, Manno, Switzerland
[b] Golgi Cenci Foundation, Abbiategrasso, Italy
[c] IRCCS—INRCA—National Institute of Health & Science on Ageing, Centre for Socio-Economic Research on Ageing, Ancona, Italy
[d] University of Milan Bicocca, Department of Sociology and Social Research, Milan, Italy

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ABSTRACT

Introduction: An ageing society poses unprecedented challenges to societies. Information and Communication Technologies (ICTs), including Social Networking Sites (SNSs), may contribute to contrast loneliness and social isolation in old age. Despite of the potentialities of SNSs, there is only a handful of studies assessing the causal relationship of SNS use and older people's well-being. This paper aims to provide further evidence on the design of randomised controlled trials exploring the causal impact of SNS use on loneliness and social isolation in old age.

Methods and analysis: The Aging in a Networked Society-Social Experiment Study (ANS-SE) is a randomised controlled trial conducted on people aged 75 and over residing in a town located in the Milan area (Italy) aiming to assess the impact of SNS use on loneliness and social isolation (i.e. the primary outcomes of this study). The study is constituted of two stages, i.e. the baseline and the follow up. The experiment is structured into one treatment group and two control groups; the interventions are the attendance to a course on SNS use (T1) and lifestyle education and brain functioning (C1). The inactive control group (C) is constituted of a waiting list. We will perform bivariate and regression analysis.

Ethics and dissemination: The study has been approved by the Ethic Committee of the University of Milano Bicocca (prot. 431/2019) and was registered at Clinical Trials.gov (NCT04242628). Written consent was obtained from all respondents. Results from the study will be discussed with the local community and stakeholders, presented in national and international conferences and published in leading peer-review journals. The consent forms, the anonymised dataset, and the relevant statistical codes will be deposited with the Italian Unidata archive, also in charge of releasing the data to the public, upon a short embargo period.

1. Introduction

Population ageing is a feature of many Western countries, including European countries. Indeed, in 2017 people aged 65+ and 80+ constitute 19.4% and 5.5% of the European Union (EU) population [1]. Population ageing has important implications both on the health care and the socio-economic systems. Within this context, the Information and Communication Technologies (ICTs) as a whole may play an important role to face the challenges posed by an ageing population. Specifically, Social Networking Sites (SNSs), such as Facebook,

Twitter, and Instagram, may contrast older people's social exclusion, contributing to keep older people informed with locally organised social events, facilitate social participation, maintain (especially long-distance) social connections, establish new social networks, and reinforce intergenerational connectedness. In short, SNSs may offer additional resources to contrast loneliness and social isolation in old age (see, amongst others: [2–4]).

Despite of the still limited but increasing use of SNSs in old age [5,6] and the claims that some authors made concerning the positive implications of SNS use for older people [7–9], there are not many studies that empirically investigated the relationship between older people's SNS use and loneliness and social isolation. When focusing on the broader concept of well-being, i.e. the cognitive and affective evaluation of one's own life [10,11], the few studies in this field have documented that SNS use has either no effect or a positive effect on different indicators of well-being, such as quality of life, social capital, loneliness and social isolation, and mental health [12–22].

However, research in this field has important limitations, mainly due to the very small and/or non-probability samples adopted and to the observational nature of most of these studies, that hamper the generalisability of the research findings and a full-understanding of the causal relationship between SNS use and well-being (of the above mentioned studies, only [13,17,18] are carried out using a randomised controlled trial design). The aim of this paper is to document the protocol adopted to conduct the first randomised controlled trial in Mediterranean Europe aimed at assessing the short and long term impact of SNS use on older people's loneliness and social isolation.

2. Methods and analysis

2.1. Overview of the study design

The Aging in a Networked Society-Social Experiment Study (ANS-SE) is part of the project Aging in a Networked Society: Older people, Social Networks and well-being (https://aginginanetworkedsociety.wordpress.com/). The ANS-SE study is a randomised controlled trial conducted on older people residing in Abbiategrasso, a town located in the Milan area (Italy) and aims to assess the short and long term impact of SNS use on loneliness and social isolation, that are the primary outcomes of this study. The study is constituted of two stages, i.e. the baseline and the follow up. The experiment is structured into one treatment group and two control groups; the intervention is constituted of the participation in a course on SNS use (T1) or on a course on lifestyle and brain functioning education (C1). The inactive control group (C) is constituted of a waiting list.

2.2. Study participants

Table 1 lists the eligibility criteria for participating in the ANS-SE study. Participants to the study are a random subsample of cognitively and physically healthy older people aged 75 and over participating to the third follow-up of the Brain Ageing in Abbiategrasso Study (InveCe.Ab study), a population-based prospective cohort study that aims to investigate the factors associated to cognitive decline in old age [23]. Eligibility for criteria 2–5 was established in two different stages of the third follow-up of the InveCe.Ab study, i.e. a visit with the medical doctors and neuropsychologists and participation in a qualitative interview on everyday life. Of the 762 participants to the third follow-up of the InveCe.Ab study, 208 were eligible for the ANS-SC study (see Table 2). The list of eligible participants was stored in a password protected computer of the member of the team in charge of the day by day management of the study (DZ).

Table 1
Eligibility criteria for the ANS-SE study.

	Criteria	Inclusion criteria	Exclusion criteria
1	Participation to the InveCe.Ab study	- Having participated to the third follow-up of the InveCe.Ab study - Having consented to be contacted to take part in further studies	- Not having participated to the third follow-up of the InveCe.Ab study - Having declined consent to be contacted to take part in further studies
2	Mental health	Geriatric Depression Scale (GDS) score less than or equal to 9	GDS score equal to or greater than 10 (no major depression)
3	Physical limitations	No physical limitations	Hands functional limitations Visual or hearing impairment
4	Cognitive health	Good cognitive functioning	Dementia or Mild Cognitive Impairment (MCI); Mini-Mental State Examination (MMSE) lower than 24
5	Experience using SNSs	No experience in using SNSs	Used SNSs at least once in life

Table 2
Overview of the research stages and number of participants at each stage.

1. Eligibility (January 2019)	
InveCe.Ab (third follow-up) study participants	*762*
-of which eligible to participate in the ANS-SC study	*208*
2. Recruitment (January 2019)	180
Contacted ANS-SC study participants	180
-of which attended the preliminary meetings (14–16/01/2019)	180
-of which were recruited (signed the consent form)	180
3. Participation at baseline and during the intervention (February-May 2019)	144
ANS-SC study participants who took part in the first assessment	144
-ANS-SC study participants who completed the intervention	137
-ANS-SC study participants who took part in the second assessment	115

2.3. Sample size calculation

There are no previous studies evaluating the causal impact of SNS use on loneliness and social isolation among our study population (i.e. older Italian adults) nor datasets available to perform the power analysis. Thus, to estimate the sample size of the ANS-SE study, we performed a power analysis on a subsample of the Survey of Health, Ageing and Retirement in Europe (SHARE), that collects information on loneliness and social isolation in old age. The subsample was selected to mirror the socio-demographic characteristics of our study population, i.e. people aged 75 and over, living in middle-size city in the North-West area of Italy. The variance between group means of the 3-items UCLA Loneliness Scale [24] and the error variance were estimated to be 31.8 and 499,5, respectively (the three groups we considered in the analysis were: older people who have not used internet or participated in any social activities in the previous week; older people who have not used internet but participated at least in one social activity in the previous week; older people who used internet in the previous week). Thus, a sample size of no less than 52 subjects per group was computed to detect the effect size of 0,25 with 80% power using a 5%-level F test of the equality of means, assuming a balanced design. However, when computing the sample size calculation, we also considered the possibility that some participants may decide to drop out of the study, once it has already started. Assuming a 10% attrition rate, the expected sample size resulted in no less than 57 subjects per group. We therefore select 60 participants per group, overall 180 individuals.

2.4. Sample selection

To perform the random selection of the 180 study participants (out of the 208 eligible individuals), one of the members of the research

team (DZ) created a computer-generated random sequence, using the website www.randomization.com. He also randomly allocated study participants to the treatment group (T1) and the active and inactive control groups (C1 and C). Random allocation was made in blocks in order to keep the size of treatment groups similar. Allocation concealment was ensured as the randomisation code was not released until study participants have been recruited into the trial.

2.5. Recruitment and participation

GCa contacted and enrolled study participants.We did not find any evidence of composition bias when controlling for differences in the demographics (i.e. gender, age and education) and cognitive (MMSE) and mental health (GDS) conditions of the three different groups. Table 2 provides an overview of the research stages and number of participants at each stage. In January 2019, we contacted by telephone the 180 study participants presenting the ANS-SE study main characteristics. After having allocated participants to the three different study groups, we invited them to take part in three preliminary meetings (one for each experimental group), that were held on January, 14th (T1), 15th (C1) and 16th (C). During the course of these meetings, we communicated the participants the type of activities they were involved in, i.e. the training course on SNS use (T1) or lifestyle education and brain functioning in old age (C1). We informed group C participants that they were put on a waiting list and that the date of the SNS course would have been communicated later in the course of the year. We also discussed in detail the contents of the consent forms, addressing participants' concerns and collected participants' signed consent forms. At the end of the meetings, we set the dates for the baseline assessments, that were held from January 21st to February 15th, 2019. We also informed participants of the dates of the follow-up study (May 2020) and encouraged them to participate. Contrary to our expectations, attrition was higher than expected. This may impact the statistical power of the study.

2.6. Intervention

The intervention group (T1) attended a three week course (two classes per week) on smartphones and SNS use. Specifically, the course covered the following topics: smartphone use, Facebook and WhatsApp use, privacy rules and fraud risk prevention using Facebook. Throughout the duration of the intervention, a tutor was available every Tuesday and Thursday to assist T1 participants in using SNSs and to collect and discuss with them possible adverse events. To implement the intervention, we provided study participants with user friendly smartphones. The intervention started on February 18th and lasted till March 7th. At the same time, the active control group (C1) attended 5 interactive 90-min meetings on lifestyle education and brain functioning in older people. These meetings covered the following topics: nutrition, brain ageing, physical activity, leisure activities, resources of the city available for older people. To enhance socialization, a goodbye tea was offered after each meeting. Throughout the duration of the intervention, we put group C study members on a waiting list (for ethical reasons, they were offered the opportunity to attend a course on SNS use at the end of the intervention, i.e. in June 2019). Originally, we planned to carry out a follow-up assessment about one year after the first intervention, i.e. in May 2020 (see registered protocol). However, due to the outbreak of Covid-19 in the Northern part of Italy and the strict lockdown introduced in the Lombardy region, we had to postponed it and rescheduled it in Autumn 2020. Study participants can leave the study at any time (for example due to health reasons or family commitments), contacting the Golgi Cenci Foundation by telephone and communicating their intentions to do so.

2.7. Assessments

Participants received a multidimensional assessment on cognitive functions (i.e. executive functions), general health, loneliness and social isolation. Trained neuropsychologists performed the neuropsychological assessments and conducted the qualitative interviews whereas geriatricians conducted the medical visits. The first and the second assessments were performed before and after the intervention, in January–February 2019 and May 2019, respectively. The second assessment entailed also the collection of study members' views and perceptions on the role of ICTs and SNSs in promoting social relationships. The neuropsychological and medical assessments were blind whereas the collection of the qualitative data were unblind, because the interview guide was dependent on the study members' group allocation. Due to financial constraints, the third assessment (postponed to Autumn 2020) will entail only an assessment of older people's loneliness and social isolation as well as the collection of their attitudes towards ICT and SNS use by means of qualitative interviews.

2.8. Measures

To measure older people's loneliness and social isolation, the primary outcomes of this study, we used the Revised UCLA Loneliness Scale [25] and the 6 item version Lubben Social Network Scale, i.e. LSNS-6 [26]. The Revised UCLA Loneliness Scale is a 20 item simplified version of the original UCLA scale designed to measure one's subjective feelings of loneliness. Study participants evaluate each item based on their perception by assigning a score varying from 1 (Never) to 4 (Often). The Revised UCLA Loneliness Scale is particularly suitable for collecting information on older study participants [27]. The Lubben Social Network Scale assesses the size and the characteristics of people's social networks. It is constituted of a 12 item scale that measures the number, the frequency and the closeness of contacts with family and friends as well as the perceived help received. We use the 6 item version (LSNS-6) which is a shorter version of the original Lubben Social Network Scale and is particularly suitable when studying older people. Both the Revised UCLA Loneliness Scale and the Lubben 6 item scale were translated using the "translation back translation" method [28].

To measure older people's cognitive functions, we used the Stroop Test [29] and three tests of the Wechsler Adult Intelligence Scale, Fourth Edition [30], i.e. the Wechsler Symbol Search, the Wechsler Coding test, and the Wechsler Digit Span, Subtest Forward, Backward and Sequencing. The Stroop Test, evaluating inhibitory control, is constituted of three trials. In the first one, the subjects read a number of written words, in the second one they name the color of the circles, in the third they name the color of the ink with which the words are written. Two scores are obtained which reflect two interference effects (time and errors). In the Wechsler Symbol Search, investigating working memory and processing speed, the subjects are required to check whether target symbols appear in line of various simple symbols as fast as possible within the allowed time. The Wechsler Coding test, investigating processing speed, consists of digit-symbol pairs followed by a list of digits: subjects are required to write down the corresponding symbol under each digit as fast as possible within the allowed time. The three sub-test of the Wechsler Digit Span, (i.e. Subtest Forward, Backward and Sequencing) investigate the short-term memory: subjects are required to repeat numbers in order (Forward), in reverse order (Backward), and from lowest to highest (Sequencing). The overall score is given by the sum of the correct answers reported in the three subtests. We used validated tests, with Italian normative values.

To assess older people's physical health we use the Cumulative Illness Rating Scale (CIRS) [31]. The CIRS is a standardized tool for detecting multimorbidity in a geriatric population. Each item is evaluated on a five-level Likert scale (from 1, no impairment to the organ/

system, to 5, extremely severe impairment) used to rate the severity of medical illness for each of 14 items referring to different domains: Cardiac; Hypertension; Vascular; Respiratory; Eye/Ear/Nose/Throat/Larynx; Upper Gastrointestinal; Lower Gastrointestinal; Hepatic; Renal; Other Genitourinary; Muscolo-skeletal-integumentary; Neurological; Endocrine-metabolic; Psychiatric/Behavioral. Each item is evaluated on an ordinal scale with increasing severity levels from 1 (absent pathology) to 5 (very serious pathology). The CIRS result represents an adequate cumulative comorbidity index in a geriatric population. Table 3 reports the schedule of ANS-SE evaluations. In writing the article, we drew on the SPIRIT reporting guidelines [32].

2.9. Data analysis plan

Data were entered in a password protected Excel sheet and stored in a password protected computer located in a locked room. To promote data quality, we implemented a number of checks (e.g., range checks for data values of validated scales and consistency checks to detect discrepancies between the data entered in the Excel sheet and those reported in the paper questionnaires during the assessments). The data analysis plan is structured into three main stages. First, for each of the three treatment groups, we will provide appropriate descriptive measures of the socio-demographic variables and outcome measures at baseline and at each timepoint. Second, after this exploratory analysis, we will perform bivariate statistical analysis, using means and percentages for quantitative and qualitative variables, respectively. We will use a number of statistical tests, to assess differences in outcome measures between the three groups. Specifically, we will use Student's t-test or Fisher's test (i.e. analysis of variance) for quantitative variables and $\chi2$ for qualitative variables. Normality of the data distributions will be tested for parametric tests. All exploratory tests will be two-tailed with alpha = 0.05. Short-term effect of treatments will be measured as net change from baseline in the outcome score (e.g UCLA Loneliness Scale). Effect sizes of between-group changes according to Cohen [33] will be also reported. A paired t-test will also be applied to compare within-group changes over time in outcome scores. Third, we will also employ multivariate analysis to investigate the associations between outcomes and treatments, controlling for possible confounding factors. Specifically, in order to eval-

uate the combined effect of treatment and time at the end of treatment period and after one year, we will perform mixed effect models which include both fixed and random effects, i.e. both between-subject and within-subject effects. We assume missing data to be missing completely at random, unless accounting for more than 10% of the sample; if item missing data is lower than 10%, listwise deletion will be used; otherwise, other approaches (e.g. Multiple Imputation) will be discussed within the research team. All analysis will be conducted using Stata release 16 [34].

3. Patient and public involvement

The draft of the protocol was first discussed in the kick-off meeting of the Aging in a Networked Society: Older people, Social Networks and well-being project. The research group and the stakeholders of the project provided feedback and comments on this first draft. During the preliminary meetings with the eligible study participants (held in January 2019), the research staff discussed the revised version of the protocol, collecting suggestions on the scheduling and content of the interventions. When drafting the journal papers, we plan to organise a number of meetings to discuss the preliminary research findings with the study participants and the stakeholders and collect insights that may enhance the interpretation of the research results. In September 2020, we will organise the final project conference and share our research findings with the scientific community, in order to receive useful comments that may improve the quality of the journal papers.

4. Conclusions

There is very little knowledge on how to design and conduct randomised controlled trials aiming at assessing the causal impact of SNS use on older people's loneliness and social isolation. We designed an innovative protocol, that has the following strengths: the recruitment is based on an existing longitudinal study of older people, it is structured in two control groups (one active and one inactive), it entails in-depth assessments of older people' social conditions as well as cognitive and physical health. The main limitation of our study is the attrition rate, that was higher than expected. Future study may evaluate the implementation of more tailored contact strategies, to reduce attrition.

Ethics

The study received approval from the Ethic Committee of the University of Milano Bicocca (prot. 431/2019) and was registered at Clinical Trials.gov (NCT04242628).

Contributors

Emanuela Sala and Daniele Zaccaria are the principal investigators of the study and lead the grant application. They jointly conceived and designed the experiment. They also wrote the paper, contributing equally to drafting it. In addition, DZ is in charge of the day-to-day management of the study and the definition of the statistical analysis plan. GCa is in charge of the organisation of the intervention. AG and RV are in charge of the medical and neuropsychological assessments, respectively. SA, ER, and LP contributed to neuropsychological assessments and the administration of the Revised UCLA Loneliness Scale and the LSNS-6. ER and GCe contributed to the drafting of the documents for the protocol registered at Clinical Trials.gov. GCe also contributed to locate the relevant literature. All authors read the manuscript.

Table 3

Schedule of study evaluations.

Collected measures	InveCe.Ab	Baseline	2 months	12 months
Primary outcomes				
20 item UCLA Loneliness Scale		X	X	X
6 item Lubben Social Network Scale (LSNS-6)		X	X	X
Cognitive and mental health				
Stroop Test		X	X	
Wechsler Symbol Search		X	X	
Wechsler Coding test		X	X	
Wechsler Digit Span		X	X	
Mini Mental State Examination (MMSE)	X			
Geriatric Depression Scale (GDS)	X			
Physical health				
Cumulative Illness Rating Scale (CIRS)		X	X	
Socio-demographic characteristics				
Gender	X			
Age	X			
Education	X			

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Data statement

Technical appendix, statistical code, and dataset available from the Data Archive for Social Sciences of the University of Milan – Bicocca (http://www.unidata.unimib.it).

Declaration of competing interest

None.

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