SOSteniamoci: An internet-based intervention to support informal caregivers

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Abstract
Objective: Informal care, defined as the unpaid care provided to an older, frail or ill person, by a person such as a spouse, parent, child, other relative, neighbour, friend, may lead to stress, burden and low well-being levels. As the phenomenon of informal care is growing, there is a need of psychological interventions in order to support informal caregivers. Evidence-based psychological treatments obtained good results in terms of well-being, but access to these treatments could be difficult for caregivers due to the of lack of time and financial strains. Internet-based interventions could be a possible solution within this scenario. "SOSteniamoci", an Internet-based Cognitive Behavioral Treatment program, consisting of 8 modules, will be adapted and tested in Italy. *Methods:* A randomized controlled clinical trial involving 128 informal caregivers will be conducted. Participants will be recruited from the Istituto Auxologico Italiano IRCCS[1] and social media advertisements. After initial screening they will be randomly assigned to either an experimental group or a waiting list group. *Expected results:* During the last decade, internet-based cognitive behavioral interventions have been developed and tested. This therapeutic approach, due to its characteristics, could be beneficial in supporting informal caregivers. We expect this intervention to be feasible and efficient in reducing caregivers' burden, anxiety, depression and stress, while improving caregivers' quality of life and the quality of relationship with the care receiver.

Keywords: Informal Caregivers; Internet-based intervention; Cognitive Behavioral Therapy; Caregiver burden; eHealth

1. Background

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[1] The Istituto Auxologico Italiano IRCCS is one of the main Italian research sites, with four main hospitals and many clinical units located in northern Italy.

1.1. The Caregiving Phenomenon: Changing Perspective for Future Interventions

Data suggest that 80% of all long-term care in Europe is provided by informal carers [1]. Informal care is defined as the unpaid care provided to an older, frail or ill person, by a person such as a spouse, parent, child, other relative, neighbor, friend or other non-kin [2]. The phenomenon of providing informal care is growing, also due to the fact that the population ages and the prevalence of chronic illnesses is increasing as well [3-6], while hospitalizations are shorter [3, 7]. The available estimates of the number of informal caregiver ranges from 10% up to 25% of the total population in Europe. National Alliance for Caregiving and AARP (2015), in the United States, estimated that 56% of caregivers are currently caring for someone. Among these caregivers, 85% are caring for a relative, whereas 15% for a friend, a neighbor or other non-relative. The estimate number of caregivers who are providing care for a parent (or parent in law) is 49%, while 12% of the caregiver population takes care of their spouses. Data reports that informal caregivers invest an average of 24.4 hours per week providing care, investment that increase for those caring for a spouse or a partner (45 hours per week) [3]. Since around 80% of the total assistance provided to non-independent people in EU is provided by informal caregivers, this estimation makes them an essential element, the backbone, of the care provided to non-autonomous people in Europe [8]. Thus, the growing number of caregivers have made caregiving a public health issue [9].

1.2. Caregiving Burden and the Resulting Need of Interventions

According to the evidence-based literature, informal caregiving may be experienced as stressful and it is often associated with a number of psychosocial and health consequences as well as financial strains, that could lead to caregiving burden [10, 11]. Caregivers’ burden can be defined as a multidimensional condition consisting of physical, psychological, emotional, social and financial stressors linked with the caregiving experience [12, 13]. In addition, due to their immense caregiving responsibilities, many caregivers report on physical exhaustion [14]and even on poor health ramifications as greater cardiovascular reactivity [15] and poor immune response; [16]. One possible explanation for these findings is that when one's commitment to the care-receiver becomes the priority, caregivers’ medical need may go unattended or neglected [17], even if many caregivers recognize that the more care they provide to themselves the more efficient they would be toward their loved ones [18]. As it has already stated, the caregiving condition could be hard to stand for those who are taking care of a loved one. Within this context, different interventions have been developed in order to ease caregivers’ stress and help them better cope with their condition. Apart from the practical support, known as respite care, that consists alleviating the caregiver from his/her duties for a while letting someone else taking care of the care recipient [19], it is possible to divide caregivers' interventions into three categories: 1) Information and educational interventions; 2) Psychosocial support interventions to reduce stress and burden; and 3) Self-care interventions that promote caregivers’ physical health [20]. Self-care interventions, specifically, aiming at promoting caregivers' physical health, are quite rare, yet studies showed that overall, they produce a decrement in the level of stress experienced by caregivers and an increment in terms of their quality of life [21].

1.3. Internet-based interventions for caregivers: using technology in order to fulfil caregivers` needs.

Due to the particular conditions that characterized caregiving phenomenon, such as financial strain, geographic constraints and the lack of time, internet-based interventions could be a possible solution in order to help caregivers and their relationships. Data from the literature reports that within the context of cancer patients, couples refused to take part of the interventions because of the lack of time [18] and because they were living too far from the intervention facilities [22]. In the same vein, higher attendance to home-based programs by caregivers (i.e. telephone counseling or technology-based interventions) has been demonstrated [23]. It seems necessary to think about something that could be efficient and feasible at the same time. The integration of dyadic interventions and technology could be useful due to it being more feasible and cost effective.
During the last decades, technology took part in our daily life and it is becoming the new goal standard also in the clinical field and health systems [24, 25]. Evidence from the literature show that thanks to internet-based interventions it is possible to reach patients from a distance [26].

Evidence also shows that internet-delivered cognitive behavioral therapy (ICBT) can be as effective as other treatment formats [27], so it can be complementary or even an alternative to face-to-face treatments [28], reducing geographical barriers both between the partners and the therapist. These interventions would be particularly useful and efficient in order to fill gaps due to caregiving condition, as they suit caregivers’ needs in term of lack of time and money.

Data from the literature showed that internet-based interventions have small to moderate beneficial effect on caregivers’ mental health, including reduction of depression, stress and anxiety [29]. Moreover, Web-based intervention programs seem to be beneficial in terms of self-efficacy, self-esteem and strain of caregivers of adults with chronic conditions [30]. Another review conducted on caregivers and internet-based interventions demonstrated that those can reduce depression and burden in caregivers, and increase self-efficacy and sense of competence, coping skills and strategies and quality of life [31].

This intervention aims at evaluating the efficacy of an internet-based intervention, culturally adapted from the Lithuanian context, for informal caregivers in Italy. Particularly, it will focus on reducing level of stress, depression and anxiety, improving the level of quality of life and quality of the relationship. It will be based on cognitive

behavioral therapy and it will consist of 8 modules. These are the themes, as listed chronologically: Introduction, Thoughts, Stress and relaxation, Problem Solving, Communication, Anxiety, Behavioral Activation, Maintenance. These themes were chosen after considering topics which might be the most useful for someone in a role of an informal caregiver, considering the trans-diagnostic nature of the intervention.
The impact of the intervention will be compared against a wait-list control group.

2. Methods

2.1. Study design

Study Type:	Interventional (Clinical Trial)
Actual Enrollment:	128 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	Participants will be randomly allocated to either control or intervention group. Participants in the control group will receive the same treatment once the intervention group is finished with the treatment.
Masking:	None (Open Label)
Primary Purpose:	Treatment

2.2. Participants

Participants will be recruited and screened for admission into the study from the Istituto Auxologico Italiano IRCCS[2] and social media advertisements. Participants will be included into the study if: 1) 18 years old or over and both gender; 2) score 24 or more points on the Caregiver Burden Inventory; 3) spent at least last couple of months for providing care; 4) must have internet access and ability to use computer or any other compatible device; 5) must be able to complete a phone interview. Exclusion criteria, instead, will be: 1) having severe physical or mental impairments, psychiatric condition or neurological disorder; 2) the person in need of care has life expectancy below or approximately around 6 months; 3) not able to use a computer or an electronic device; 4) not able to complete a phone interview; 5) score 23 or less points on the Caregiver Burden Inventory.

2.3. Measures

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[2] The Istituto Auxologico Italiano IRCCS is one of the main Italian research sites, with four main hospitals and many clinical units located in northern Italy.

Primary outcome:

Caregiver Burden Inventory (CBI) [Time Frame: Pre-treatment, week 4, week 8- and 12-month post-treatment]

This measure is used to evaluate caregiver burden. CBI contains 24 questions that are distributed within 5 facets - Time Dependency, Emotional Health, Development, Physical Health and Social Relationships. Answer options are presented on a 5-item Likert scale and ranges from from 0 ('Never') to 4 ('Nearly Always'). Total score on CBI is summed up and ranges from 0 to 96, higher score indicating higher levels of burden experienced.

Secondary outcomes:

1. *Perceived stress scale (PSS-14)* [32][Time Frame: Pre-treatment, week 8 and 6 months post-treatment]
   Measure will be used to evaluate levels of experienced stress. It contains 14 questions on a Likert scale ranging from 0 ('Never') to 4 ('Very Often'). Higher score indicates more severe symptoms.
2. *The Patient Health Questionnaire (PHQ-9)* [33][Time Frame: Pre-treatment, week 8 and 6 months post-treatment]
   Measure will be used to evaluate depressive symptoms. It contains 9 questions that must be responded to by choosing an answer from 4-item Likert scale, where number 0 indicates 'Not at all' and 3 - 'Nearly every day'. Higher score indicates more severe symptoms.
3. *Generalized anxiety disorder (GAD-7)* [34][Time Frame: Pre-treatment, week 8 and 6 months post-treatment]
   Measure will be used to evaluate caregiver anxiety. GAD-7 contains 7 questions that must be responded to by choosing an answer from 4-item Likert scale, where number 0 indicates 'Not at all' and 3 - 'Nearly every day'. Higher score indicates more severe symptoms.
4. *World Health Organization (WHO-5)* [35] [Time Frame: Pre-treatment, week 8 and 6 months post-treatment]
   This questionnaire contains 5 statements regarding individual's well-being. Each of the statements must be evaluated using 6-item Likert scale with a score of 0 indicating 'At no time' while a score of 5 - 'All the time'. Higher score indicates higher well-being.
5. *Couples Satisfaction Inventory (CSI-4)* [36] [Time Frame: Pre-treatment, week 8 and 6 months post-treatment]
   This questionnaire contains 4 statements regarding couple satisfaction. Each of the statements must be evaluating using 6-item Likert scale. Higher score indicates higher couple satisfaction.
   The questionnaire will be translated and back translated into the target language (Italian) based on its original English version in order to ensure that the wording is appropriate. This will be done in line with the recent recommendations of Swami and Barron (2018). Moreover, it will be adapted to different kind of relationship between caregiver and care receiver, not only spousal relationships.

2.4. Procedure

Arm	**Intervention**
Experimental: Intervention group Trans-diagnostic, 8 modules, 8 week long internet intervention for reducing informal caregiver burden	*Behavioral: Intervention group* Intervention based on cognitive behavioural therapy principles and culturally adapted to Italian population. Intervention's main purpose is to reduce caregiver burden and increase quality of life and relationship. Intervention contains psycho-educational elements as well as examples and exercises.
No Intervention: Control group Participants in the control group will be instructed to wait. Once intervention group will be finished, participants in control group will be able to access the same intervention	

Opening the website, participants will be provided with information on inclusion and exclusion criteria, as well as the registration process, management and research team. After participants provide informed consent on a secure study website, they will be asked to complete the screening questionnaires. Participants will then be invited for a telephone interview. Following telephone interviews, the final decision on participation in the study will then be discussed jointly and agreed by the two co-authors (MS and GP). The decision on exclusion or inclusion in the study will be communicated to participants within a few days. After randomization, participants in the intervention and wait-list control groups will be provided with information about the start of the intervention. Participants in the Waiting-list control group will also be told that they will be able to receive access to the same treatment once the intervention group is finished.

A secure online *iterapi* platform [37] will be used for communication between therapists and participants, the distribution of program materials and the collection of evaluations. The participant's personal information will be made anonymous by assigning each participant a code, which will then be used to access the program. The included participants will also be able to extend their data security by receiving the code on their phone numbers. Code that must be entered at each time they log in, after their self-generated password.

At the beginning of the intervention, all participants will receive an email containing their username and a personalized link to create their password. Throughout the program, participants received an email every Thursday indicating the availability of the new material. Participants who do not view the week's material or have not conducted exercises will receive a weekly reminder. The memo will contain a short encouraging message and will be sent on Monday, from therapists to participants in their groups.

2.5. Randomization procedure

All participants will be randomly assigned to the Experimental or Control group. The randomization scheme will be generated using the Web site Randomization.com (http://www.randomization.com). Randomization will occur after the baseline measurements.

2.6. Sample size calculation

The minimum sample size required to conduct this study was computed by using an a-priori sample size calculator (G*Power 3.1.9.2 software) for Fisher f's tests [38, 39]. Participants will be measured with at three time points: (1) at treatment beginning, (2) at the end of the treatment, and (3) at six months follow-up. Treatment condition (experimental group vs. control group) was classified as between-group variable, and time was classified as within-group variable. The a-priori partial η2 was set to assume a value of 0.020 – small effect size [40] – that provides a Cohen's f equal to 0.143. Moreover, the Type I error (α) rate was set at 0.05 (two-sided) and the Power (1 - β) was set at 0.80, according to general guidelines [40]. The a-priori correlation between repeated measures was set at 0.20 – small correlation [40]. Finally, sphericity was assumed. Results showed that there is an almost 80% chance of correctly rejecting the null hypothesis of no significant effect of the interaction with 64 subjects per group for a total of 128 participants.

3. Expected results and conclusion

During the last decade, internet-based cognitive behavioral therapy (ICBT) has been developed and tested in different control trials. This therapeutic approach, due to its characteristics, could be beneficial in supporting informal caregivers. We expect this intervention will be feasible and efficient in reducing caregiver burden, stress, depression and anxiety, while improving the quality of life and the quality of relationship. Data will be collected through a secure *iterapi* platform during pre-post and follow-up.

References

1. Hoffmann, F. and R. Rodrigues, *Informal carers: who takes care of them?* 2010.
2. Triantafillou, J., et al., *Informal care in the long-term care system European overview paper.* 2010.

3. Caregiving, N.A.f., *Caregiving in the US 2015.* NAC and the AARP Public Institute. Washington DC: Greenwald & Associates, 2015.
4. Castelnuovo, G., et al., *Chronic care management of globesity: promoting healthier lifestyles in traditional and mHealth based settings.* Frontiers in Psychology, 2015. **6**: p. 1557.
5. Castelnuovo, G., et al., *Managing chronic pathologies with a stepped mHealth-based approach in clinical psychology and medicine.* Frontiers in psychology, 2015. **6**: p. 407.
6. Ratti, M.M., et al., *Social support, psychological distress and depression in hemodialysis patients.* Psicologia della Salute, 2017.
7. Panzeri, A., S.R. Ferrario, and G. Vidotto, *Interventions for Psychological Health of Stroke Caregivers: A Systematic Review.* Frontiers in psychology, 2019. **10**: p. 2045.
8. Naiditch, M., et al., *User perspectives in long-term care and the role of informal carers*, in *Long-Term Care in Europe*. 2013, Springer. p. 45-80.
9. Schulz, R. and T.L. Patterson, *Caregiving in geriatric psychiatry.* The American Journal of Geriatric Psychiatry, 2004. **12**(3): p. 234-237.
10. Metzelthin, S.F., et al., *Positive and negative outcomes of informal caregiving at home and in institutionalised long-term care: a cross-sectional study.* BMC geriatrics, 2017. **17**(1): p. 232.
11. Hwang, B., et al., *Caregiving for patients with heart failure: impact on patients' families.* Am J Crit Care, 2011. **20**(6): p. 431-41; quiz 442.
12. Li, Q.P., Y.W. Mak, and A.Y. Loke, *Spouses' experience of caregiving for cancer patients: a literature review.* Int Nurs Rev, 2013. **60**(2): p. 178-87.
13. Pottie, C.G., et al., *Informal caregiving of hospice patients.* J Palliat Med, 2014. **17**(7): p. 845-56.
14. Pressler, S.J., et al., *Family caregiver outcomes in heart failure.* Am J Crit Care, 2009. **18**(2): p. 149-59.
15. Vitaliano, P.P., J. Zhang, and J.M. Scanlan, *Is caregiving hazardous to one's physical health? A meta-analysis.* Psychological bulletin, 2003. **129**(6): p. 946.
16. Lutgendorf, S.K. and M.L. Laudenslager, *Care of the caregiver: stress and dysregulation of inflammatory control in cancer caregivers*. 2009, American Society of Clinical Oncology.
17. Coristine, M., et al., *Caregiving for women with advanced breast cancer.* Psycho-Oncology: Journal of the Psychological, Social and Behavioral Dimensions of Cancer, 2003. **12**(7): p. 709-719.
18. Hunstad, I. and M.F. Svindseth, *Challenges in home-based palliative care in Norway: a qualitative study of spouses' experiences.* International journal of palliative nursing, 2011. **17**(8): p. 398-404.
19. Mason, A., Weatherly, H., Spilsbury, K., Arksey, H., Golder, S., Adamson, J., & Glendinning, C. (2007). A systematic review of the effectiveness and cost-effectiveness of different models of community-based respite care for frail older people and their carers. In *NIHR Health Technology Assessment programme: Executive Summaries*. NIHR Journals Library.

20. Revenson, T. A., Griva, K., Luszczynska, A., Morrison, V., Panagopoulou, E., Vilchinsky, N., Hagedoorn, M. (2016). *Caregiving in the illness context.* 1st edn. New York, NY: Palgrave Macmillan.
21. Gemmill, R., et al., *Informal caregivers of hematopoietic cell transplant patients: a review and recommendations for interventions and research.* Cancer Nurs, 2011. **34**(6): p. E13-21.
22. Baucom, D.H., et al., *A couple-based intervention for female breast cancer.* Psycho-Oncology: Journal of the Psychological, Social and Behavioral Dimensions of Cancer, 2009. **18**(3): p. 276-283.
23. Toseland RW, Haigler DH, Monahan DJ. *Education and Support Programs for Caregivers: Research, Practice, Policy*. Springer, New York (2011).
24. Liverpool, S., et al., *Engaging Children and Young People in Digital Mental Health Interventions: Systematic Review of Modes of Delivery, Facilitators, and Barriers.* Journal of Medical Internet Research, 2020. **22**(6): p. e16317.
25. Castelnuovo, G., et al., *Obesity and outpatient rehabilitation using mobile technologies: the potential mHealth approach.* Frontiers in psychology, 2014. **5**: p. 559.
26. Cattivelli, R., et al., *ACTonHEALTH study protocol: promoting psychological flexibility with activity tracker and mHealth tools to foster healthful lifestyle for obesity and other chronic health conditions.* Trials, 2018. **19**(1): p. 1-11.
27. Andersson, G., et al., *Guided Internet-Based CBT for Common Mental Disorders.* Journal of Contemporary Psychotherapy, 2013. **43**(4): p. 223-233.
28. Andersson, G., et al., *Internet-supported versus face-to-face cognitive behavior therapy for depression.* Expert Rev Neurother, 2016. **16**(1): p. 55-60.
29. Sherifali, D., et al., *Impact of Internet-Based Interventions on Caregiver Mental Health: Systematic Review and Meta-Analysis.* J Med Internet Res, 2018. **20**(7): p. e10668.
30. Ploeg, J., et al., *Caregiver-Focused, Web-Based Interventions: Systematic Review and Meta-Analysis (Part 2).* J Med Internet Res, 2018. **20**(10): p. e11247.
31. Guay, C., et al., *Components and Outcomes of Internet-Based Interventions for Caregivers of Older Adults: Systematic Review.* J Med Internet Res, 2017. **19**(9): p. e313.
32. Mondo, M., C. Sechi, and C. Cabras, *Psychometric evaluation of three versions of the Italian Perceived Stress Scale.* Current Psychology, 2019.
33. Arroll, B., et al., *Validation of PHQ-2 and PHQ-9 to screen for major depression in the primary care population.* Ann Fam Med, 2010. **8**(4): p. 348-53.
34. Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of internal medicine*, ***166***(10), 1092-1097.
35. Heun, R., Bonsignore, M., Barkow, K., & Jessen, F. (2001). Validity of the five-item WHO Well-Being Index (WHO-5) in an elderly

population. *European archives of psychiatry and clinical neuroscience*, **251**(2), 27-31.

36. Funk, J.L. and R.D. Rogge, *Testing the ruler with item response theory: increasing precision of measurement for relationship satisfaction with the Couples Satisfaction Index.* J Fam Psychol, 2007. **21**(4): p. 572-83.
37. Vlaescu, G., et al., *Features and functionality of the Iterapi platform for internet-based psychological treatment.* Internet Interv, 2016. **6**: p. 107-114.
38. Faul, F., et al., *Statistical power analyses using G*Power 3.1: tests for correlation and regression analyses.* Behav Res Methods, 2009. **41**(4): p. 1149-60.
39. Faul, F., et al., *G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences.* Behav Res Methods, 2007. **39**(2): p. 175-91.
40. Cohen, J., *Statistical power analysis for the behavioral sciences*. 2 ed1988, Hilsdale, N.J.: Lawrence Earlbaum Associates.