

The effect of written information and counseling by an APN on resilience in women with vulvar neoplasia during six months after surgical treatment and the influence of social support, recurrence, and age: A secondary analysis of a multicenter randomized controlled trial, WOMAN-PRO-II

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Abstract

Background Woman with vulvar neoplasia complain after surgical treatment often about physical and psychological distress. Lack of information and support can influence resilience. Whether an information-related intervention through an advanced practice nurse support resilience and which other factors have an influence on resilience in women with vulvar neoplasia has never been investigated.

Methods The aim of this study were (a) to analyse whether counseling based on the WOMAN-PRO-II program compared to written information creates a significant improvement in resilience scores of women with vulvar neoplasia and (b) to identify potential predictors for resilience. A randomized controlled trial was carried out in women with vulvar neoplasia (N = 49) six months after a surgical treatment in four Swiss hospitals and one Austrian hospital. Analyses of resilience and its predictors were performed using a linear mixed model.

Results The resilience score did not differ significantly between the two intervention three and six months after randomisation ($p=0.759$). As significant predictors of resilience, age ($b=.04$, $p=0.001$), social support ($b=.28$, $p=0.009$), counseling time ($b=.03$, $p=0.018$), and local recurrence ($b=-.56$, $p=0.009$) could be identified in linear mixed models analyses.

Conclusion To promote resilience in women with vulvar neoplasia, the WOMAN-PRO II Program should be further developed. Particularly, social support should be extended, e.g. in form of more frequent consultations. The interrelation between recurrence and resilience needs to be further investigated to provide specific counseling for women with recurrence.

Background

Vulvar neoplasia includes vulvar intraepithelial neoplasia as a precancerous cellular change, as well as vulvar cancer as a cancerous cellular change in the external female genitalia [1]. While a rare disease, vulvar neoplasia incidence has increased globally over the past decade, especially among younger women [2]. In Germany, the incidence of vulvar cancer increased from 1.6 cases per 100,000 women annually in 1974 - 1978 to 7.9 in 2009 - 2013 [3].

Surgical treatment is considered the standard intervention for vulvar neoplasia [4]. Despite surgical advances, women in the postsurgical phase experience physical and psychosocial symptoms, including pain, fatigue, and altered self-image, as well as emotional and interpersonal distress or uncertainty [5, 6]. Additionally, vulvar neoplasia remains a stigmatized condition, associated with poor hygiene or promiscuity [5]. As a result, affected women feel isolated and are often unable to speak about their disease [7, 8].

In the literature, it is well-established that cancer treatment and the accompanying symptom-related distress present significant adversity, which can lead to negative outcomes such as post-traumatic stress disorder, depression, and anxiety [9, 10]. Studies describe resilience as an important factor in overcoming

such adversities. Resilience is a multidimensional concept, defined in different ways. The author of this paper interprets resilience as a capacity and dynamic process to cope successfully with significant change or adversity and can be facilitated through interventions [9, 11].

Important elements relating to the concept of resilience in cancer patients include confidence, self-transcendence of the disease, and self-esteem. Confidence is characterized by the perception that one has control over environmental circumstances [12]. In adverse circumstances, such as cancer treatment and symptom-related distress, uncertainty can lead to loss of control. Haase (2004) states that uncertainty arises when people lack sufficient information about the treatment or do not understand information they receive [12].

While uncertainty and symptom-related distress vary with cancer type and treatment, they are especially pronounced in cancers associated with taboos and stigmatization [6, 13]. Moreover, phenomenological studies have shown that women with vulvar neoplasia experienced a general lack of information about symptom management and strategies to manage handle their situation [5, 7].

We developed a new information-based intervention focusing on self-management of post-surgical symptoms. In this program, women with vulvar neoplasia are taught to use a symptom diary to help them recognize and assess symptoms at different levels; for example, wound-related symptoms, difficulties, feelings, thoughts, and behaviours. The assessment of symptoms and distress are discussed in a nurse-led consultation, focused on tailored information, motivational interviewing, self-management, and behavioural change [6, 13].

A systematic review indicates that interventions for promoting resilience in cancer patients are mainly psychology-based, such as stress management and resilience training programs or positive psychology group interventions. Notably, interventions were predominantly examined in women with breast cancer; no study investigated resilience in women with vulvar neoplasia [14].

It is unclear if nurse-led information-related interventions influence resilience among women with vulvar neoplasia, or what other aspects contribute to resilience in this population. With growing interest in resilience in cancer care, it is important to understand how nurses can support women with vulvar neoplasia and help them adapt to adverse circumstances. Therefore, the aim of the present study was, (a) to investigate the effect of systematic counseling by an Advanced Practice Nurse (APN) compared to written information about resilience among women with vulvar neoplasia six months after surgery, and (b) to examine the influence of social support, age, counseling duration, and local recurrences on resilience among women with vulvar neoplasia three and six months after surgery.

Methods

Study design

This study is a secondary analysis of quantitative data from the mixed methods project WOMAN-PRO II (clinical trial ID: NCT01986725). The quantitative part of the WOMAN-PRO II study was a two-arm, multicenter, randomized controlled parallel-group phase II trial with two interventions and repeated measures during six months. The primary outcome of this study was the symptom prevalence in women with vulvar neoplasia over six months after surgical treatment. Results focusing on this outcome are published elsewhere [15].

The present secondary analysis examines the effect of written information (intervention I) and systematic counseling by an APN (intervention II) on resilience in woman with vulvar neoplasia at baseline as well as three and six months after a surgery. Further, we tested whether social support, age, consulting time and local recurrence have an influence on resilience in woman with vulva neoplasia.

Interventions

The contents of the two interventions are described in table 1. Participants in intervention I received standard care and written information, while participants in intervention II additionally received systematic counseling by an APN with a focus on promoting self-management of post-surgical symptoms. A detailed description of the interventions can be found in a prior study [15].

Insert table 1.

Sample and setting

Data was collected from September 2013 until May 2015 in four Swiss hospitals (two regional and two university hospitals) as well as in one Austrian university hospital.

The sample size calculation was driven by the symptom scores observed in a previous study [6]. A total sample of 90 women for both arms was required. Further, an attrition rate of 15% was added so that 106 women were needed for recruitment. The randomization ratio was 1:2 (intervention I: n = 30, intervention II: n = 60), based on the recommendation of Dodd et al. (2001) in favor of counseling at the expense of written information [16].

We included women over 18 years after a vulvar intraepithelial neoplasia or vulvar cancer diagnosis and with planned surgical treatment in one of the designated hospitals. Women who were terminally ill or not able to complete the questionnaire for cognitive, linguistic, emotional or physical reasons were excluded.

Randomization

A nurse or physician in the ambulatories or on the ward invited eligible women to participate in the study. A computer-generated block randomization list with one stratification factor (vulvar intraepithelial neoplasia or vulvar cancer) was generated. After having signed the informed consent, eligible women were randomized to intervention I or II. Sequentially numbered and opaque sealed envelopes were used to guarantee allocation concealment. Envelopes were prepared by persons not involved in the study. To

determine group allocation, the APN opened the envelopes in numerical order in front of the patient and assigned her to intervention I or II.

Data focusing on resilience and social support were collected at three time points: at diagnosis (t0), three months post-surgery (t3), and six months post-surgery (t4). Consultation took place at five time points, beginning at diagnosis (t0) and ending six months (t4) post-surgery. Medical data, e.g. local recurrence, were collected seven days after surgery (t1) and socio-demographic data were charged once at t0.

Owing to the nature of the intervention, blinding of participants was not possible. However, participating women and healthcare staff were blinded to group assignments and differences between the two interventions. Additionally, external quality audits based on the guidelines of the National Cancer Institute were conducted in both intervention groups [17]. The aim of the audit was to review (1) the study progress, (2) adherence to the study protocol, (3) the APN's counseling knowledge, and (4) case reports of randomly selected study records.

Measurements

Sociodemographic- and medical data

Sociodemographic data were collected by means of an 11-item scale concerning age, marital status, number of children, education, employment status, living situation, post-surgical wound management at home, and health insurance. Medical data were collected using a 16-items form concerning diagnosis, cancer stage, initial treatment, and wound treatment. Both questionnaires were developed for the WOMAN-PRO II study and tested previously [6].

Connor-Davidson Resilience Scale (CD-RISC)

Resilience was assessed by means of the author-approved German translation of the 10-item Connor-Davidson Resilience Scale (CD-RISC 10). This unidimensional instrument reflects the ability to bounce back from a variety of challenges such as illness, emotional pressure or painful feelings. Items are rated on a 5-point scale (0 = „not true at all“ to 4 = „true nearly all the time“) providing a total sum score ranging from 0 to 40, with higher scores reflecting greater resilience [10]. The German translation of the CD-RISC 10 has acceptable psychometric properties with high internal consistency (Cronbach's alpha = 0.84) [18]. The internal consistency at baseline of CD-RISC 10 in this study was very high ($\alpha_{t0} = 0.89$).

Multidimensional Scale of Perceived Social Support (MSPSS)

Social support was assessed using the German version of the 12-item Multidimensional Scale of Perceived Social Support (MSPSS) [19]. This instrument measures the perceived adequacy of social support from family, friends and significant others. These aspects form three subscales with four items each. Items are rated on a 7-point scale (1 = „very strongly disagree“ to 7 = „very strongly agree“). Higher scores on each of the subscales indicate higher levels of perceived support. The mean of the three subscales reflects global satisfaction with perceived social support. Internal consistency of the original

scale is high (Cronbach's alpha = 0.88) and construct validity is adequate [19]. The internal consistency at baseline of MSPSS in this study was very high ($\alpha_{t0} = 0.86$).

Counseling time

Invested counseling time was listed by the APN after each consultation.

Statistical analysis:

We used descriptive statistics (frequencies, median, interquartile range) to characterize basic properties of our sample. Group difference in socio-demographic and medical data at baseline were assessed using non-parametric tests (Mann-Whitney-U-test and Fisher's exact test).

Mean scores were calculated for the CD-RISC and MPSS scale. Furthermore, linear mixed models were used to determine differences between treatment arms across the time points and to assess the impact of other factors like age, social support, consulting time, and local recurrence on resilience. Step by step, variables were integrated into the model, based on a significant change in $-2LL$. Apart from main effects, we also investigated significant interactions. We did not find any significant change over time. Therefore, it was not necessary to adapt the covariance structure. Based on graphical techniques (residuals plots, Q-Q-plots) and appropriate tests (Kolmogorow-Smirnow) we ensured the assumptions of mixed linear models to hold.

A two-tailed p-value of 0.05 was chosen to represent statistical significance. We performed statistical analyses using the IBM SPSS Statistics for Windows (version 23.0) based on the intention-to-treat principle.

Results

Of 93 eligible patients, 49 were included in the analysis. Forty-four of the eligible women refused to participate due to feeling overburdened, time constraints, missing trust or loss of interest in the research. During the follow-up phase a total of thirteen women (26.5%) dropped out, primarily because they were no longer available after being transferred to another hospital. The process of patient recruitment, randomization and follow-up is presented in the publication of the primary outcomes [15].

The sociodemographic characteristics of the sample is shown in table 2. Participants' age ranged from 24 to 81 years ($Mdn = 57.0$; IQR = 47.0; 66.0). A total of 31 women (63.3%) had a vulvar cancer diagnosis and nine women (18.4 %) a local recurrence. Twenty-one of 49 women (42.9 %) were married and 33 (67.3%) had ten or fewer school years. No significant difference could be observed between the two groups in terms of demographic or clinical characteristics at baseline.

Insert table 2.

The linear mixed model shows no significant difference with regard to resilience and the two intervention arms ($p = 0.759$). In addition, the scores were not statistically different between the groups at the three time points ($p = 0.345$). The course of resilience over the three time points for both intervention arms is displayed in Figure 1.

Insert figure 1.

Moreover, the results of the linear mixed model indicate a significant impact on resilience for „local recurrence“ ($p = 0.009$) „age“ ($p = 0.001$) „global social support“ ($p = 0.009$), and „counseling time“ ($p = 0.018$). Whereas „age“, „global social support (MSPSS)“ and „counseling time“ have a positive influence, „local recurrence“ shows a negative impact on resilience. The joint influence of „age“ and „counseling time“ is significant as well ($p = 0.006$), with decreasing impact of the duration of counseling as age increases. Details are shown in table 3.

Insert table 3.

Discussion

The aim of this study was to evaluate the effect of written information and counseling by an APN on resilience in women with vulvar neoplasia after surgical treatment. In addition, we investigated the influence of social support, age, duration of counseling and local recurrences on resilience in women with vulvar neoplasia three and six months after surgery. The results show that there is no significant difference between the two groups with regard to resilience. Furthermore, the findings indicate that social support, longer duration of counseling and higher age showed higher resilience, whereas local recurrence showed a lower resilience score. Finally, we found that the six-months period has no influence on resilience.

To our knowledge, this is the first study exploring the effect of information-related interventions on resilience in women with vulvar neoplasia. One explanation for the non-significant results could be that the benefit of the intervention is noticeable at a later time and more time is needed for adaptation, probably due to the dynamic process of resilience [9]. Studies of a currently published review generally investigated data over an average five year-period [20]. Another possible reason could be that counseling on symptom control or additional written information are not enough to promote resilience. This may indicate that multimodal interventions are necessary to foster resilience in cancer care. Loprinzi et al. (2011) achieved a significant increase in resilience in women with breast cancer by means of stress management and resilience training. Their program is based on Attention and Interpretation Therapy. Attention training includes exercises supporting persons to abandon prejudices in favor of a more flexible disposition. It intends to cultivate skills such as gratitude, compassion, acceptance, forgiveness, higher meaning, and purpose [21]. Roseberg et al. (2018) recently reviewed their PRISM intervention in

adolescents and young adults with cancer. PRISM is a skills-based intervention aimed at stress management, goal-setting, cognitive reframing, and benefit finding [22].

Another explanation for the non-significant results could be the small sample size. Due to the rarity of the disease and a large number of attritions, it was not possible to recruit the desired number of patients.

The results of the linear mixed models reveal that resilience was positively associated with age. Previous studies on individuals with colorectal cancer and the general population as well as on healthy populations support our result that older age is associated with higher resilience [23, 24].

Cohen et al. (2013) point out that patients with cancer show lower emotional distress with advancing age. Similarly, higher age is associated with better emotional regulation and problem-solving competence in the general population [25]. Probably, persons with higher age were confronted with other adverse circumstances (e.g. divorce or the death of a loved one) resulting in positive problem-solving strategies [26].

Besides, our analysis indicates that the impact of consulting time decreases with increasing age. In contrast, Dubey et al. (2015) showed that age moderates the association between resilience and unmet information, with a marginally stronger negative relation for patients aged 65 and older [27].

Furthermore, our results show that a higher level of perceived social support predicts higher resilience. Social support can have various sources such as family, friends or significant others [28]. Previous studies confirm the buffering effect of social support allowing the affected person to talk about problems. This contributes to reduced stress and higher emotional well-being [29]. Qualitative studies demonstrate that women with vulvar neoplasia are ashamed of talking about their disease and they feel alone [8, 30]. However, Rügsegger et. al (2018) also describes that women feel supported if they find a person they can trust [30]. Studies also show that social support can also relate to instrumental or financial aspects. This seems to be important especially for younger patients [31].

The present study revealed that resilience was positively associated with longer counseling time. One possible explanation for the positive relationship between resilience and counseling time may be that a longer period of counseling contributes to resolve disease-related uncertainties and to develop effective problem-solving strategies [13]. Further, women report that they feel safe and secure that arose through confidence that the APN actively took time for talking to them and discussing their concerns. In difference to the other medical staff, who were perceived as busy, the APN explicitly took time to talk to the patients[30]Through these results, it can be assumed that through time and continuity confidence can be built and this contributes to the development of resilience. Furthermore, it may be possible that the feeling of control was enhanced by the additional information they received [12].

Finally, the present findings reveal that resilience is negatively correlated with recurrent disease. In a descriptive study, Dubey et al. (2015) showed that resilience in patients with different types of cancer

does not correlate with recurrence [27]. Probably, recurrence promotes hopelessness and leads to lower resilience [32] as well as fear and uncertainty about the further course of the disease [13, 33].

Limitations

This study has several limitations. First, it is possible that the small sample sizes distorted the results. Second, this study did not account for potential confounders, such as time since the cancer diagnosis or other sociodemographic variables (e.g. education, marriage). The short duration of the study did not allow to assess the long-term effect of the intervention on the development of resilience. Third, we excluded participants with mental disorders, thereby increasing the risk of bias, as resilience correlates with different mental disorders, e.g. depression or anxiety [10]. This study focussed global social support. Therefore, it would be important to investigate different types of social support, such as instrumental or financial support.

Finally, some participants might have experienced other types of traumatic events that were not fully assessed.

Conclusion

In conclusion, the results show that the WOMAN-PRO II Program should be further developed to promote resilience and to support women with vulvar neoplasia in facing cancer-related distress. Furthermore, the findings indicate that perceived social support, particularly in the form of communication (systematic counseling), is crucial for developing resilience in woman with vulvar neoplasia. This should be considered with regard to further development of the intervention, e.g. by increasing the intensity of consultations with a prolonged counseling period, more counseling sessions or active involvement of family members. Moreover, age and individual experience should also be taken into consideration. This means that younger women and persons who have not yet experienced adversity need more attendance.

In a further study, the negative relationship between resilience and recurrence should be explored in women with vulvar neoplasia in order to detect unmet supportive care needs and to understand the related dynamic of resilience.

With regard to written information, no implications for clinical practice can be derived on the basis of the results. As far as counseling is concerned, predictors indicate that its implementation may be useful to promote resilience in women with vulvar neoplasia. Further research is needed to validate this hypothesis. To achieve a larger sample size, more hospitals should participate. Additionally, the recruitment phase should be prolonged and the follow-up phase extended to at least two years.

Abbreviations

APN Advanced Practice Nurse

Declarations

Ethics approval and consent to participate

The study was approved by the leading ethics commission in Berne “Ethikkommission des Kantons Bern”, member of swissethics (committee’s reference number: 035/13) and by all local ethics committees of the participating clinics. The objectives, importance, risk and benefits of the research and data confidentiality were explained to all participants before recruitment. Written informed consent was obtained from all patients.

Consent for publication

Not applicable

Availability of data and materials

The data that support the findings of this study and trial protocol are available from the corresponding author, (Sabine Kofler), upon reasonable request.

Competing interests

The authors declare that they have no competing interests with respect to research, authorship, and/or publication of this article.

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Author Contributions

SO and SK analyzed and interpreted the patient data regarding resilience and written information and counseling by an APN. SK has written the original draft. AK performed data curation, review and editing. BS did the conceptualization, review and editing of the manuscript. All authors read and approved the final manuscript.

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This study adheres to CONSORT guidelines.

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Tables

Table 1.
Description of the two interventions arms

	Written information (intervention I)	Counseling based on the WOMAN-PRO II Program (intervention II)
<i>Intervention</i>	- Standard care and written information	- Intervention I and counseling by an APN or nurse with equivalent education.
<i>Mode of delivery</i>	- Face-to-face	- Face-to-face & phone
<i>Content</i>	Set of leaflets including: <ul style="list-style-type: none"> - wound care after discharge - healthcare services in hospital and community (e.g. psycho-oncologist) 	Nurse-led follow-up consultations, including: <ul style="list-style-type: none"> - symptom self-assessment with the WOMAN-PRO Symptom Diary (Senn et al., 2013) (based on four domains: wound-related symptoms, psychosocial symptoms, difficulties in daily life, and information needs) - healthcare services - decision-making
<i>Based on</i>	<ul style="list-style-type: none"> - Standard care: local standards and existing guidelines (DGGG, 2015; Royal College of Obstetricians and Gynaecologists [RCOG], 2014) - Written information: developed by a group of clinical experts 	- Evidence-based counseling guideline (Kobleider et al., 2016)
<i>Intensity</i>	<ul style="list-style-type: none"> - 10 to 30 minutes - During hospitalisation and routine follow-up (three and six months after discharge) 	<ul style="list-style-type: none"> - 10 to 50 minutes - one-week post-surgery, two weeks after discharge, three months post-surgery, and six months post-surgery
<i>Implementation</i>		<ul style="list-style-type: none"> - training programm (12 hours) - opportunity to receive supervision during study

Table 2.

Sample characteristics at baseline by intervention

Characteristics	Written information (n = 13)	counseling (n = 36)	p	Total
Number of patients per country; n			.53 ^a	
Austria	7	15		22
Switzerland	6	21		27
Age (years); Mdn (IQR)	57.0 (45.0; 69.0)	56.5 (45.5; 64.5)	.62 ^b	57.0 (47.0; 66.0)
Missing; n (%)	0 (0.0)	6 (16.7)		6 (12.2)
Marital status; n			.19 ^a	
Married	8	13		21
Single/widowed/divorced	5	22		27
Missing; n (%)	0	1 (2.8)		1 (2.0)
Children			.28 ^a	
Having at least 1 child; n	10	20		30
no children	2	13		15
Missing; n (%)	1 (7.7)	3 (8.3)		4 (8.2)
Educational level; n			.52 ^b	
10 or fewer school years	8	25		33
>10 years	5	10		15
Missing; n (%)	0 (0.0)	1 (2.8)		1 (2.0)
local recurrence, n			1.00 ^a	
Yes	3	6		9
No	9	22		31
Missing; n (%)	1 (7.7)	8 (22.2)		9 (18.4)
Type of vulvar disease			.74 ^a	
Vulvar intraepithelial neoplasia	4	14		18
Vulvar squamous cell carcinoma	9	22		31
Missing; n (%)	0 (0.0)	0 (0.0)		0 (0.0)
Counselling time (minutes); Mdn (IQR)	—	30.0 (20.0; 45.00)	—	30.0 (20.0; 45.00)
Missing; n (%)	—	9 (25.0)		9 (25.0)
MSPSS mean score ^c , Mdn (IQR)	6.6 (6.3; 6.9)	6.7 (6.0; 7.0)	.95 ^b	6.6 (6.1; 7.0)
Missing; n (%)	3 (23.1)	8 (22.2)		11 (22.4)

Resilience mean score ^d Mdn (IQR)	3.4 (2.5; 3.8)	3.2 (2.7; 3.7)	.51 ^b	3.3 (2.6; 3.7)
Missing; n (%)	3 (23.1)	8 (22.2)		11 (22.4)

Mdn = median; *IQR* = interquartile range (1. quartile; 3. quartile); MSPSS Multidimensional-Scale-of-Perceived-Social-Support; *p* = *p*-value

^a Fisher's exact test

^b Mann-Whitney-U-test

^c Likert-scale ranges from 1 to 7; high scores indicate higher levels of perceived social support

^d Likert-scale ranges from 0 to 4; higher values mean higher resilience

Table 3.

Linear mixed models analyses predicting the change of resilience

	b	t	p	95% CI
Local recurrence (0 = no, 1 = yes)	-.56	-2.70	.009	-.98, -.14
Age	.04	3.40	.001	.01, .06
Counseling (minutes)	.03	2.44	.018	.01, .06
Social support	.28	2.72	.009	.07, .49
Time	-.09	-.95	.345	-.27, .10
Age*Counseling	-.0008	-2.88	.006	-.001, -.002

Figures

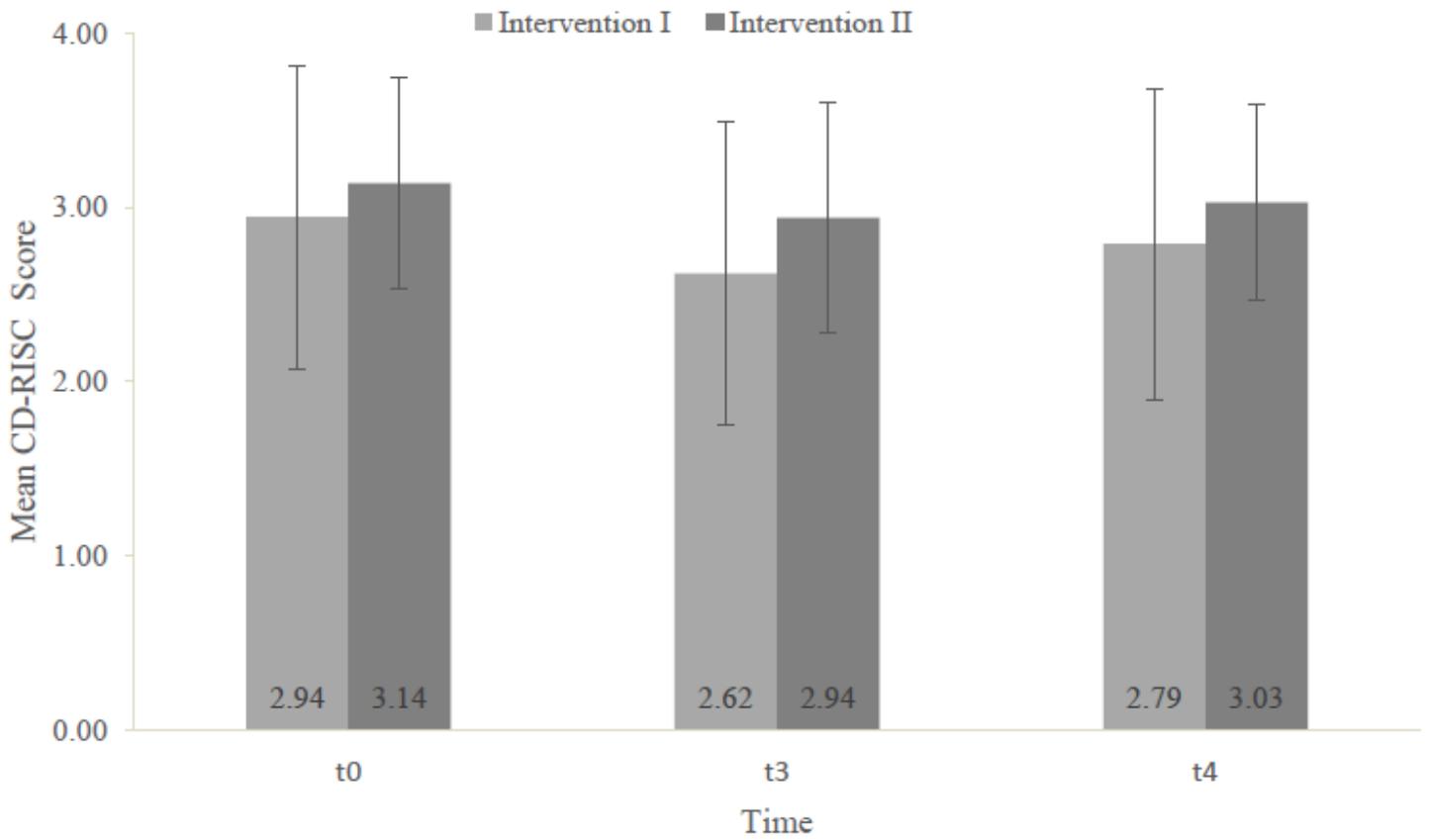


Figure 1

Resilience scores (mean; standard deviation) of the two intervention arms at the three time points.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [20191018CONSORT2010Checklist.doc](#)