

# Telemedical care improves quality of life in patients with schizophrenia and bipolar disorder. Results of a randomized controlled trial

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## Research article

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# Abstract

Background Schizophrenia and bipolar disorder are serious psychiatric disorders with a high disease burden, a high number of years of life lived with disability and a high risk for relapses and re-hospitalizations. Besides, both diseases are often accompanied with a reduced quality of life. A low level of quality of life is one predictor for relapses. This study examines whether a telemedical care program can improve quality of life.

Methods Post stationary telemedical care of patients with severe psychiatric disorders" (Tecla) is a prospective controlled randomized intervention trial to implement and evaluate a telemedical care concept for patients with schizophrenia and bipolar disorder. Participants were randomized to an intervention or a control group. The intervention group received telemedical care including regular, individualized telephone calls and SMS-messages. The quality of life was measured with the German version of the WHOQOL-BREF. Effects of telemedicine on quality of life after 6 months were analyzed using t-tests to compare the intervention with the control group. Participants also evaluated the telemedical care program based on a short standardized interview.

Results 118 participants were recruited, thereof 57.6% men (n = 68). Participants were on average 43 years old (SD) 13). The IG showed higher QoL scores as the control group (CG) 6 months after baseline for the WHOQOL total sum score (t-test (CI) 93.1 (92.4-93.8) vs 89.7 (88.8-90.6),  $p < 0.0001$ ) and for 4 of 5 domains: Global 62.0 (60.9-63.0) vs. 56.8 (55.6-58.1),  $p < 0.0001$ ; Physical health 63.8 (63.0-64.7) vs. 59.6 (58.5-60.6),  $p < 0.0001$ ; Psychological 60.9 (60.0-61.9) vs. 56.4 (55.1-57.6),  $p < 0.0001$ ; Environment 70.8 (70.1-71.6) vs. 67.5 (66.7-68.3),  $p < 0.0001$ .

Conclusion The Tecla telemedical care concept has improved the quality of life in patients with severe psychiatric disorders. It provides for a low-threshold and well suitable component in psychiatric treatment.

## Introduction

Mental disorders have a high disease burden and the number of days with limitations is 3 times higher in afflicted patients than for healthy people [1]. The course of mental diseases is often chronic [2]. Schizophrenia and bipolar disorder are among the most serious psychiatric disorders. Schizophrenia is one of the ten diseases with the highest number of years of life lived with disability (YLD) [3]. Relapses and re-hospitalization are frequent in patients with schizophrenia and bipolar disorder [4, 5]. Both diseases are often accompanied with a distinct impairment of social and professional life management and hence result in a lasting reduced quality of life [3, 6–8]. The World Health Organization Quality of Life (WHOQOL) Group defined quality of life as the "individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." [9]. All aspects of life, which means physical, social, environmental and psychological aspects, affect one's wellbeing and satisfaction [6].

Schizophrenia and bipolar disorder patients show similar levels of quality of life [6]. A low level of quality of life is a predictor for relapses [10]. Akvardar et al. showed that the improvement of quality of life is one important part in treating psychiatric disorders [7]. Hence, quality of life is an important factor and must be a target for gaining a good or at least stable state of mental health [7, 11].

Telemedicine has the potential to improve the health care situation for patients within the mental health spectrum. Positive effects were shown on patients with anxiety and depression [12] and on medication adherence in patients with schizophrenia and bipolar disorder [13].

This paper reports results regarding quality of life from a prospective controlled randomized intervention trial called “Post stationary telemedical care of patients with severe psychiatric disorders” (Tecla). Tecla’s objective was the implementation and evaluation of a telemedical care concept for patients with schizophrenia, schizoaffective disorder and bipolar disorder. It addressed different problematic issues in treatment and every-day-life-management [14]. Primary outcome was medication adherence, which was positively influenced by the telemedical care concept [13]. This article aims to investigate the effects of the telemedical care concept on the quality of life of patients with schizophrenia, schizoaffective disorder and bipolar disorder. The hypothesis is that the participants of the intervention group, which received additional telemedical care, had better levels of quality of life compared to participants of a control group, which received usual care six months after baseline.

## **Materials And Methods**

### **Patient sample and data**

Data were retrieved from the prospective controlled randomized intervention trial Tecla. Inclusion criteria of Tecla were a medical diagnosis of any form of schizophrenia (ICD-10 F20), schizoaffective disorders (ICD-10 F25), or bipolar disorders (ICD-10 F31), and age  $\geq 18$  years. The diagnoses were extracted from the patient files. Exclusion criteria were prior scheduled inpatient treatments within the next six months and lacking reachability by cell phone. The participants were recruited shortly before their discharge from day-care hospitals or open or locked inpatient wards from three psychiatric departments in Western-Pomerania, a Federal State in the very northeast of Germany.

Tecla has been approved by the Ethics Committee of the University Medicine Greifswald (BB 122/14) and was registered at the German Clinical Trials Register (date 2015\05\21, DRKS00008548). A comprehensive description of the study protocol for the Tecla study was published by Stentzel et al. [14].

### **Randomization**

The participants were randomized to the intervention or control group after the baseline assessment. A blinded scientist, who was neither involved in the recruitment nor in the baseline assessment, performed the allocation to the groups using a random allocation (block randomization). The listing of the two

groups was unregularly. The participants were chronically signed to the next entry in the randomization list.

## **Telemedical intervention**

Participants were individually randomized to intervention group and control group. Both groups received care as usual in the outpatients facilities (outpatient psychiatric / psychotherapeutic practices or psychiatric institutional outpatients' departments). The intervention group received regular telephone calls every two weeks and in addition standardized as well as individualized text messages every week. An example for such an individualized text message is given in Fig. 1. Qualified nurses who are specialized in telemedical care conducted the regular telephone calls. The nurses are embedded in regular meetings within one of the psychiatric institutional outpatients' department and day-care hospital. They were trained in the documentation system and join appropriate psychiatric/psychotherapeutic education programs. The telemedical conversation was conducted on the basis of eCRFs in a computer-aided documentation system in accordance with the current standards for data security and data privacy [15, 16]. The standardized conversation contained a structured standardized and an individualized part. The structured standardized part of the telephone calls included suicidal tendencies, changes in the medication regime, medication adherence and medication side effects (study protocol published elsewhere [13]). The individualized part addressed selected topics of everyday life that the respective participant evaluated as important for himself and his condition. The weekly text messages refer to actual and relevant events and themes in the daily life of the participants.

## **Measures**

### **WHOQOL-BREF**

The quality of life was measured with WHOQOL-BREF, the short version of the subjective instrument World Health Organization Quality of Life, which is designed for generic use [9, 17]. It assesses the quality of life from a subjective perspective [7]. The short version WHOQOL-BREF has 26 items. Answers are given on 1-to-5-point Likert scales. The higher the sum score the better the quality of life of the patient [17]. WHOQOL assesses different aspects of life that are relevant for quality of life [9]. The WHOQOL-BREF bases on four domains [9, 17] and one global value for general quality of life:

Physical domain: pain, energy, sleep, mobility, activities, medication, work.

Psychological domain: positive feelings, cognitions, self-esteem, body image, negative feelings, spirituality.

Social relationships: personal relationships, social support, sex.

Environment: safety and security, home environment, finance, health/social care, information, leisure, physical environment, transport.

Global: overall quality of life, general health.

The German version was used, which shows good internal consistence (Cronbachs  $\alpha > 0.7$  for all domains) for the overall population as well as for patients with mental disorders [18].

## Participants' evaluation of the telemedical care program

Participants of the intervention group were asked to evaluate the telemedical care at the end of their study participation by answering the questions shown in Table 1.

Table 1

Interview questions and answers to assess acceptance and satisfaction of the participants

<b>Question:</b>	<b>How would you assess the telephone and text messages contacts during the last 6 months?</b>
<b>Answer:</b>	Very helpful – little helpful – not helpful – other (free text) – don't know – no answer
<b>Question:</b>	Could you imagine continuing the telephone contacts in this form?
<b>Answer:</b>	Yes – No – don't know – no answer
<b>Question:</b>	Do you think this kind of care can partly replace personal contacts with physicians or psychologists?
<b>Answer:</b>	Yes – No – don't know – no answer
<b>Question:</b>	Is there something you would change or improve?
<b>Answer:</b>	Yes – No – don't know – no answer and additional free text

## Statistical analysis

The baseline characteristics were compared by group affiliation to identify any group differences at baseline. We used t-tests for continuous variables and Chi-square tests for categorical variables. To analyze effects of the telemedical intervention on quality of life, the WHOQOL total sum score and each of the WHOQOL domains of the intervention group were compared with the scores of the control group after 6 months using t-tests.

The analyses were conducted with the intention-to-treat approach. For randomized clinical trials with missing data the multiple imputation procedure is a valid method to handle missing data [19] and to minimize possible biases [20]. However, a required condition for multiple imputation is, that missing data are distributed completely at random (MCAR) or at random (MAR), whereas the method is less appropriate for data missing not at random (MNAR) [21]. After thorough inspection, we appraised the missing data as MAR. The proportions of missing values ranged from 11–17% (WHOQOL-variables 12%). Hence multiple imputation was proceeded. To be able to reproduce the results, each time the analysis is performed the random seed value was specified [19]. Eighteen variables were included in the imputation model. Minimum and maximum values for score values were defined. Further details are documented in

the supplement. All statistical procedures were performed in SAS 9.4 (© 2002–2012 by SAS Institute Inc., Cary, North Carolina, USA.).

## Results

118 participants were recruited (see CONSORT flow diagram in Fig. 2), thereof 57.6% men (n = 68). Participants were on average 43 years old (standard deviation (SD) 13). Baseline characteristics are shown in Table 2. Except for education, there was no significant difference between the intervention and control group at baseline. Participants in the intervention group had a better education than participants in the control group. 104 diagnoses of schizophrenia and schizoaffective disorder (ICD-10 F2x.) and 48 bipolar disorder-diagnoses (ICD-10 F3x.) were found. 21 patients had two to three diagnoses. Further details are documented in Table 1 the supplement. 90 participants remained in the study until the six-month follow-up. Of these, 79 participants completed the WHOQOL-BREF.

Table 2

Characteristics of the participants at baseline. The differences between the intervention and control group were analyzed for categorical variables with Chi<sup>2</sup> and for continuous variables with a t-test.

Chi <sup>2</sup>	Total n (%)	Intervention group n (%)	Control group n (%)	p- value
Participants	118 (100)	58 (49.2)	60 (50.8)	
Female	50 (42.4)	27 (22.9)	23 (19.5)	0.3664
Psychiatric disease*				0.4734
Schizophrenia / Schizoaffective disorder (ICD-10 F2x.)	104 (68.4)	52 (34.2)	52 (34.2)	
Bipolar disorder (ICD-10 F3x.)	48 (31.6)	21 (13.8)	27 (17.8)	
Education:				0.0002
< 10 years	32 (32.3)	6 (6.1)	26 (26.3)	
10 years	42 (42.4)	25 (25.3)	17 (17.2)	
> 10 years	25 (25.3)	17 (17.2)	8 (8.1)	
Employment:				0.3483
Not employed	98 (85.2)	45 (39.1)	53 (46.1)	
Marginally employed	5 (4.4)	3 (2.6)	2 (1.7)	
Employed	12 (10.4)	8 (7.0)	4 (3.5)	
Social living situation:				0.9299
Living alone	56 (51.4)	27 (24.8)	29 (26.6)	
Living with spouse, partner or assisted living	53 (48.6)	26 (23.9)	27 (24.8)	

Chi <sup>2</sup>	Total n (%)	Intervention group n (%)	Control group n (%)	p- value
t-test	Total mean (SD)	Intervention group mean (95% CI)	Control group mean (95% CI)	p- value
age	42.9 (13.0)	43.9 (40.5– 47.4)	42.0 (38.6– 45.2)	0.4099
WHOQOL total score	87.2 (14.0)	86.8 (83.0– 90.8)	87.6 (83.6– 91.2)	0.7927
WHOQOL domains:				
Global	49.3 (21.0)	46.0 (39.9– 52.2)	52.4 (46.8– 58.0)	0.1246
Physical health	56.3 (16.7)	56.8 (51.9– 61.5)	55.8 (51.2– 60.5)	0.7931
Psychological	56.3 (17.2)	56.8 (51.9– 61.7)	55.8 (51.1– 60.6)	0.7740
Social relationships	57.3 (21.3)	53.7 (48.0– 59.3)	60.7 (54.5– 66.9)	0.0938
Environment	66.1 (15.2)	66.3 (62.2– 70.5)	65.9 (61.5– 70.3)	0.8826
*Higher overall numbers because some patients had both diagnoses, CI = confidence interval				

The results of the analysis of quality of life after six-months are shown in Table 3. Both the total sum score as well as the separate domains show significant differences between intervention and control group. The intervention group showed higher quality of life scores between 3.3–5.2 points for the global, physical health, psychological and environmental domain. Whereas the control group showed a significantly slightly better score within social relationships.

Table 3  
Analysis of differences in quality of life between intervention and control group at six-month-follow-up using t-test

	<b>Intervention group mean (95% CI)</b>	<b>Control group mean (95% CI)</b>	<b>p-value</b>
WHOQOL total score	93.1 (92.4–93.8)	89.7 (88.8–90.6)	< 0.0001
WHOQOL domains:			
Global	62.0 (60.9–63.0)	56.8 (55.6–58.1)	< 0.0001
Physical health	63.8 (63.0-64.7)	59.6 (58.5–60.6)	< 0.0001
Psychological	60.9 (60.0-61.9)	56.4 (55.1–57.6)	< 0.0001
Social relationships	58.2 (57.3–59.1)	61.1 (59.9–62.3)	0.0002
Environment	70.8 (70.1–71.6)	67.5 (66.7–68.3)	< 0.0001
CI = confidence interval			

Results of sensitivity analyses are shown in the supplement. Differences in intervention-group-means between baseline and six-month follow-up without multiple imputation (MI) are shown in supplement Table 2 and with multiple imputation (MI) in supplement Table 3. Differences in means between the intervention and control group in the six-month follow-up without and with multiple imputation (MI) are shown in supplement table 4.

The results of the evaluation of the telemedical program by participants of the intervention-group are shown in Fig. 3. Participants perceived the telemedical care mostly as moderately to very helpful (97.5%, Fig. 3A). A majority would like to continue the telemedical care (73.2%, Fig. 3B). A minority can even imagine, that the tele medical care can make contacts to doctors or psychologists less necessary or perhaps can partly replace them (34.2%, Fig. 3C).

## Discussion

Quality of life is a major treatment goal for patients with psychiatric disorders [7, 11, 23]. A low-threshold telemedical care program containing regular telephone calls and SMS-messages was able to improve quality of life compared to a control group in almost all aspects. These findings are in line with another study that also investigated a mobile health (mHealth) approach. Ben-Zeev (et. al) compared the mHealth intervention FOCUS with a widely used group self-management intervention called WRAP [24]. As one of the secondary outcomes quality of life was investigated. The FOCUS participants showed significant improvements between baseline and the six months follow up. Even though the FOCUS intervention substantially differs slightly from Tecla, the mode of administration via information and communication technologies is similar. The general feasibility, acceptance and efficiency of electronic Health (eHealth)

and mHealth interventions for people with serious mental illnesses is proven by several other studies [25–27].

However, the WHOQOL was proven as an adequate tool for assessing quality of life in different cultures and population groups [28, 29]. Therefore, in this study we have adopted a generic tool [6], that can be broadly applied for assessing quality of life in different cultures and population groups [30, 31]. The WHOQOL-BREF is less affected by disease-related factors [17] and has been applied in patients with schizophrenia with good reliability and validity [31, 32], even in psychotic stages, on medication and in patients with relatively low education level [7]. Kim et al. compared patients' assessments of their own quality of life with WHOQOL-BREF with assessments of proxies (such as family members, caregivers) and found a moderate to good accordance between both assessments of the patients' quality of life [8].

Even though schizophrenia and bipolar disorder are different diseases, there are similarities between them like the extent of quality of life. Both diseases showed similar scores for the WHOQOL-BREF domains in previous studies [11, 33]. In this study, the baseline characteristics showed no differences between the diagnostic groups (see Table 2). Hence, we analyzed both diseases together.

A strength of this study is the usual care setting with only little inclusion and exclusion criteria. Consequently, the results are likely to be transferable to a large part of the patient group and daily regular medical care. In this regular care setting, the study was conducted with a RCT-design. To fortify the validity, a multiple imputation was performed.

The baseline assessment showed a significant difference between the two groups with respect to the level of education. Participants in the intervention group had a higher level of education compared to participants in the control group. A blinded scientist performed the allocation to the groups using a random allocation (block randomization) after the baseline assessment. However, the baseline characteristics showed similar values for all WHOQOL-domains for both groups (see Table 2). In fact, the intervention group had even slightly lower WHOQOL total score values. The intervention was largely standardized. Furthermore, the loss to follow-up was identical in both groups (see Fig. 2). Therefore, a systematic bias seems unlikely. The proportion of loss to follow-up at the six-month-follow-up was 24% in the invention group and 23% in the control group. Due to the size of the dropout rates, there might be an attrition bias [34, 35], but threshold levels for acceptable dropout-levels are not determined in guidelines yet [35]. Furthermore, distinct patient clienteles might require different levels. Because of the almost identical rates and because of the difficult patient clientele, we deem that potentially bias might be low. Besides, the loss to follow-up is similar to other reported dropout rates in the regarded patient groups [31].

Diagnoses were extracted from the patients' files from the three recruiting psychiatric departments. In several cases, a clear diagnosis has not yet been made by the treating physicians. Therefore sometimes several diagnoses were applied here.

Medication and its side effects could possibly effect patients' quality of life [11] and would have been informative, but these aspects were not included here. However, it is a relevant question. Hence, the

influence of medication on various data collected within the Tecla study, including the quality of life aspect, is currently being evaluated.

## **Conclusion**

Every aspect that can help to stabilize the patient and avoid hospitalization should be considered during treatment. The telemedical intervention shown here is a low-threshold care concept that has the potential to improve the care situation of patients with severe psychiatric diseases. Schulze et al. showed before that Tecla improved medication adherence [13]. Here we studied Tecla's impact on overall quality of life of the participants. Quality of life concerns the personal, subjective perspective of life and has a high relevance for the patients. The Tecla telemedical care intervention addressed both general and individual issues of daily life of the participants. The intervention was successfully integrated in the usual care practice of the patients.

The Tecla intervention has considerable potential to complement usual care and can help to avoid treatment gaps or re-hospitalization. Hence, it should be considered a suitable and appropriate treatment component for patients with severe psychiatric diseases.

## **Abbreviations**

CI	Confidence interval
DF	Degree of freedom
eCRF	Electronic Care Report Forms
eHealth	Electronic health
MAR	Missing at random
MCAR	Missing completely at random
MNAR	Missing not at random
mHealth	Mobile health
MI	Multiple imputation
OR	Odds ratio
SD	Standard deviation
Tecla	Study “Post stationary <b>telemedical</b> care of patients with severe psychiatric disorders”
WHOQOL	World Health Organization Quality of Life
WHOQOL-BREF	World Health Organization Quality of Life, short form with 26 items
YLD	Years of life lived with disability

## Declarations

### Ethics approval and consent to participate

Tecla is approved by the Ethics Committee of the University Medicine Greifswald (BB 122/14). The committee stated that the majority of the members of the committee concluded that there are no ethical and legal concerns against the implementation of the study, and therefore approves the proposal. Tecla is retrospectively registered at 2015\05\21 at the German Clinical Trials Register (DRKS00008548). All patients had to sign an informed consent to participate. If appropriate legal guardians or representatives were informed about the participation. All guardians or representatives indicated that the patients were capable of providing ethical consent to participate.

### Consent for publication

Not applicable.

## Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

## Competing interests

The authors declare that they have no competing interests.

## Funding

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## Authors' contribution

NvdB, HJG and WH designed the study. LNS, HJG, JS, JML and NvdB participated in the coordination of the patient recruitment. US and LNS coordinated the study. US conducted the statistical calculation with support from JS. US drafted the manuscript. WH provided comprehensive feedback to an early draft. All authors read and approved the final manuscript.

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## Figures

### **Study nurse:**

Good morning Mrs. XX, this is Sister YY from the telephone study from Greifswald. Were you still in the “Klex” yesterday for choir practice and how did you like it? could you get the medicine from the pharmacy yesterday? I would appreciate an answer from you. Sunny greetings sister YY

### **Participant:**

Good morning, yes I was in the “Klex” yesterday and I picked up the pills today and took them. Right now I'm sitting at my GP's getting an ECG. Love XX

Figure 1

Example for an individualized text message contact between study nurse and participant

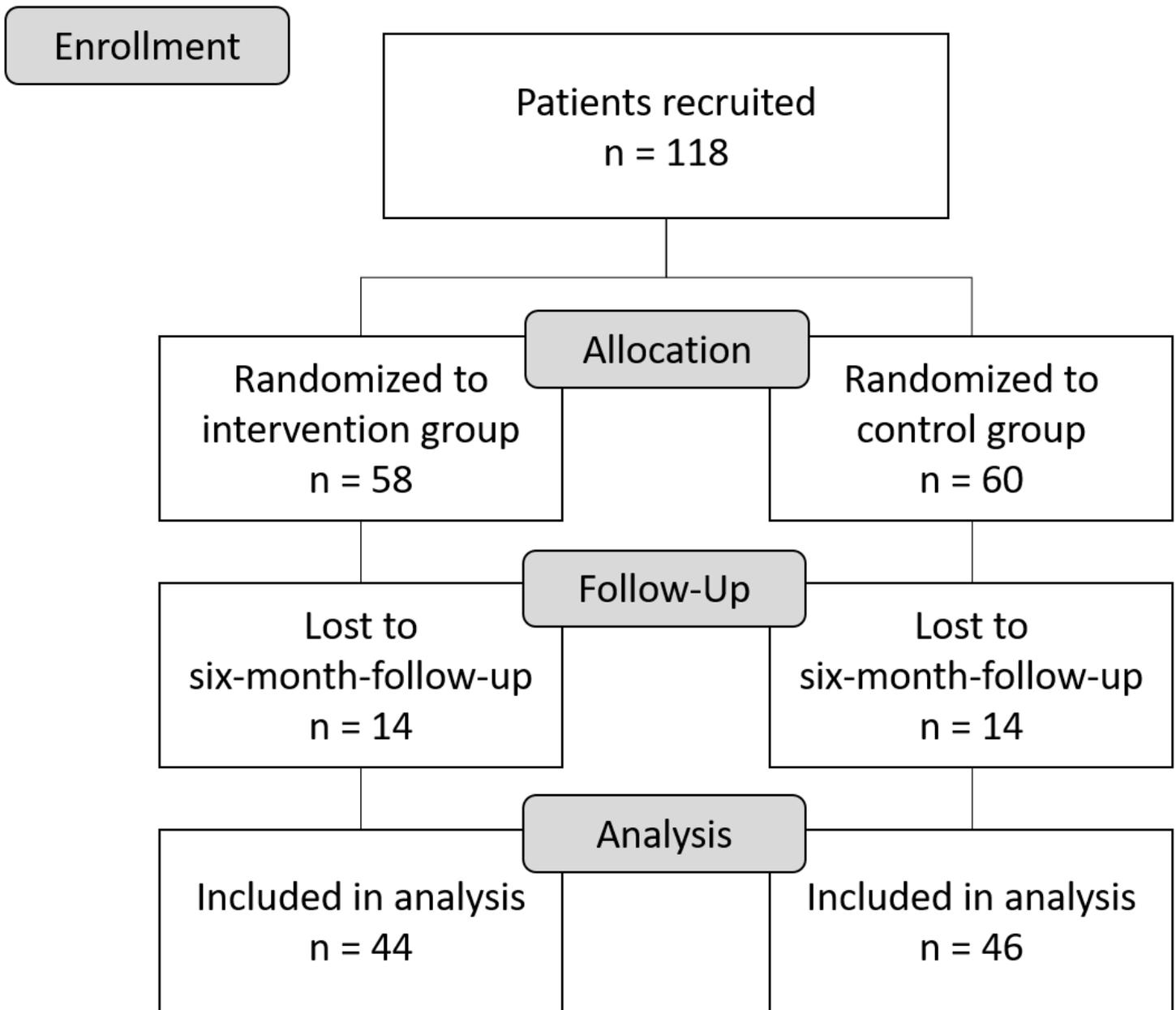
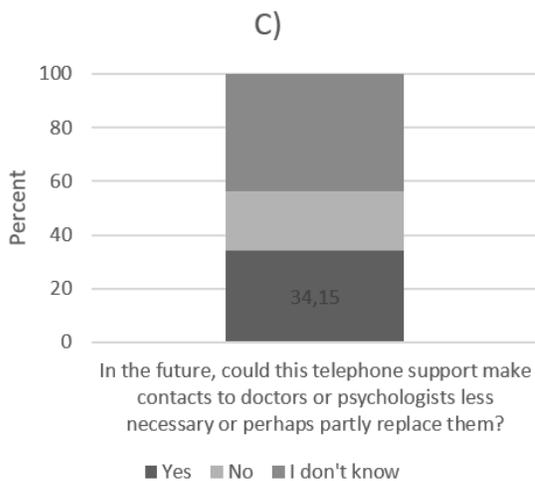
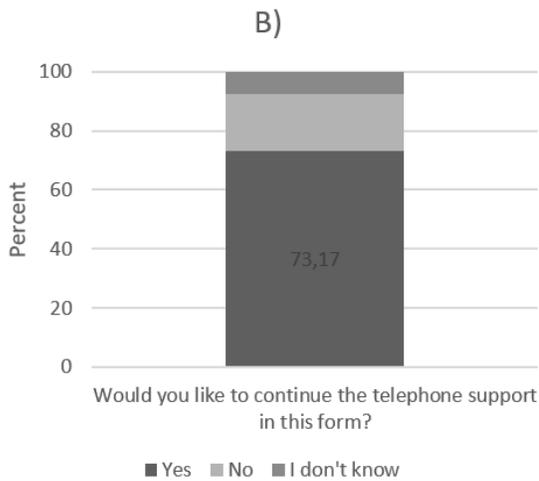
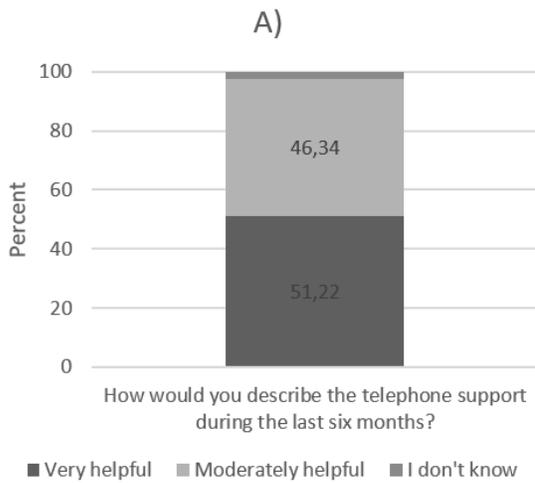


Figure 2

CONSORT flow diagram [22]



**Figure 3**

Subjective evaluation of received telemedicine care by the participants of the intervention group

## Supplementary Files

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

- [CONSORT2010ChecklistTecla.doc](#)
- [SupplementMultipleImputation.docx](#)