

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

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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). Linear mixed model revealed that affiliation to patient group (0 = CG, 1 = IG), gender (0 = female, 1 = male), increasing social support and higher GAF-level are positive significant influence factors for the WHOQOL total quality of life, physical, psychological, environmental and global domain. An increasing education often showed significantly decreasing quality of life values. Age as an influencing factor, showed different results on the sum score and the individual domains.

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.

Trial registration: German Clinical Trials Register, DRKS00008548, registered 21 May 2015 – retrospectively registered, https://www.drks.de/drks_web/setLocale_EN.do

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 ≥ 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 Figure 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. Summing all 26 items gives total quality of life, ranging from 26 to 130 [18]. The higher the 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 domain: personal relationships, social support, sex.
- Environment domain: safety and security, home environment, finance, health/social care, information, leisure, physical environment, transport.

- Global value: 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 [19].

Social support

Social support was assessed using the measure F-SozU (Social support, short form with 14 items) [20]. The authors defined social support as the result of cognitive-emotional processing and assessment of current and past social interactions. The concept is based on cognitive approaches and assesses the subjective conviction to get support from the subject's social network if necessary. This 14-item short form is appropriate for the assessment of a more generally perceived social support [20]. The statements refer to the fields of emotional support (to be liked and accepted by others, to share feelings, to experience participation), to provide practical assistance (practical help in everyday problems, for example to borrow things, getting practical advice, getting help with challenging tasks) and social integration (belonging to a circle of friends, doing joint ventures, knowing people with similar interests) and are assessed using a 5 category Likert-scale from "does not apply" (scored 1) to "applies exactly" (scored 5) [20, 21].

Global assessment of functioning (GAF)

The Global Assessment of Functioning (GAF) is an overall measure of how patients are doing from positive mental health up to severe psychopathology [22]. It is known, that functioning is low in people with current mental health disorders, so functioning can be used as an expression of the severity of illness [23]. The GAF-questionnaire measures the degree of mental illness by rating psychological, social and occupational functioning [22] on an ordinal scale from 1 to 100 [24]. The scale is divided into 10-point intervals. The lowest interval (score 1 to 10) represents severe illness, the highest interval (score 91 to 100) represents the healthiest condition [21, 22].

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

Question:	How would you assess the telephone and text messages contacts during the last 6 months?
Answer:	Very helpful - little helpful - not helpful - other (free text) - don't know - no answer
Question:	Could you imagine continuing the telephone contacts in this form?
Answer:	Yes - No - don't know - no answer
Question:	Do you think this kind of care can partly replace personal contacts with physicians or psychologists?
Answer:	Yes - No - don't know - no answer
Question:	Is there something you would change or improve?
Answer:	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. A linear mixed model regression was calculated to test for the intervention effects. The computation was performed using SAS PROC MIXED (SAS 9.4 © 2002-2012 by SAS Institute Inc., Cary, North Carolina, USA.). For parameter estimation, a minimum variance quadratic unbiased estimation (MIVQUE0) was performed, using unstructured covariance matrices. The WHOQOL total quality of life as well as each of the WHOQOL domains and the global value were the respective dependent variable. As fixed effects served the affiliation to the patient group, age, gender, education, social support, and the Global Assessment of Functioning (GAF). The subjects served as random effect. In order to control for the time of assessment (baseline and 6-month-follow-up), a repeated statement was included in the model. Results are considered statistically significant when P-values are 0.05.

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 [25] and to minimize possible biases [26]. 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) [27]. 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 [25]. 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 Figure 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 χ^2 and for continuous variables with a t-test.

	Chi ²	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)	
	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
Social support		48.9 (13.1)	48.8 (10.8-15.8)	48.9 (11.3-16.6)	0.9480
GAF		55.3 (11.0)	55.5 (9.1-13.2)	55.2 (9.7-14.0)	0.8951
WHOQOL total quality of life		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, GAF = Global Assessment of Functioning

Results of the linear mixed model regressions are shown in Table 3. With respect to the study group affiliation the intervention group has significantly better values in quality of life in the total quality of life, in all WHOQOL-domains except for social relationships and the global value. That is to say that the values of the intervention group were significantly lower for the social relationships domain.

Table 3: Results of the linear mixed model for WHOQOL total sum score and the five WHOQOL Domains^a

	Intercept	Patient group (0 = CG, 1 = IG)	Age (years)	Sex (0 = female, 1 = male)	Education (0 < 10 years, 1 = 10 years, 2 > 10 years)	Social support (observed max score: 70)	GAF (observed max score: 99)
WHOQOL total quality of life (observed max score: 120)	49.93 ± 1.149	3.133 ± 0.412	-0.001 ± 0.016	7.031 ± 0.390	-1.083 ± 0.283	0.363 ± 0.016	0.267 ± 0.013
	p <.0001	p <.0001	p = 0.9909	p <.0001	p = 0.0001	p <.0001	p <.0001
WHOQOL Physical health (observed max score: 97)	26.11 ± 1.479	3.763 ± 0.515	-0.096 ± 0.020	6.196 ± 0.488	0.096 ± 0.356	0.132 ± 0.021	0.397 ± 0.017
	p <.0001	p <.0001	p <.0001	p <.0001	p = 0.7880	p <.0001	p <.0001
WHOQOL Psychological (observed max score: 98)	19.97 ± 1.671	4.109 ± 0.616	-0.073 ± 0.023	10.34 ± 0.585	-2.215 ± 0.424	0.342 ± 0.023	0.279 ± 0.018
	p <.0001	p <.0001	p = 0.0017	p <.0001	p <.0001	p <.0001	p <.0001
WHOQOL Social relationships (observed max score: 100)	5.454 ± 1.707	-1.214 ± 0.609	0.140 ± 0.023	2.013 ± 0.578	-5.807 ± 0.420	0.791 ± 0.024	0.191 ± 0.019
	p = 0.0014	p = 0.0465	p <.0001	p = 0.0005	p <.0001	p <.0001	p <.0001
WHOQOL Environment (observed max score: 99)	32.14 ± 1.296	3.141 ± 0.472	0.093 ± 0.018	5.773 ± 0.448	1.234 ± 0.325	0.418 ± 0.018	0.081 ± 0.014
	p <.0001	p <.0001	p <.0001	p <.0001	p = 0.0001	p <.0001	p <.0001
WHOQOL Global (observed max score: 100)	11.97 ± 1.827	1.970 ± 0.625	-0.035 ± 0.024	8.127 ± 0.594	-3.858 ± 0.435	0.234 ± 0.025	0.485 ± 0.022
	p <.0001	p = 0.0017	p = 0.1468	p <.0001	p <.0001	p <.0001	p <.0001

Abbreviations: IG = intervention group, CG = control group, GAF = Global Assessment of functioning

^aEstimated regression coefficient ± standard error,

Regarding age the results varies. A significant increase with increasing age was observed for the domains social relationships and environment. In contrast, the physical and psychological health domain showed a significant decline with increasing age. Likewise, a decline with increasing age was observed for the total quality of life and global domain, albeit not significant.

A significant influencing factor is the participants' gender. Being male showed higher values for the WHOQOL sum score and all domains.

To control for the observed differences at baseline, the level of education (0 < 10 years, 1 = 10 years, 2 > 10 years) was included in the model. The results show a very heterogeneous picture. The WHOQOL total quality of life, psychological and social relationships domains and the global values significantly decreases with increasing education. The physical health domain increases with increasing education, but not significant. In contrast, increasing education increases the environment domain significantly.

Regarding the influence of social support on quality of life, it was observed for all domains, the total quality of life and the global value that the values increase significantly with increasing social support.

With increasing level of the Global Assessment of functioning as a measure for the impairment of the participants, the WHOQOL total quality of life and all of the four domains and the global value increased significantly. The increasing ranges from 0.1 – 0.5 points though.

The results of the evaluation of the telemedical program by participants of the intervention-group are shown in Figure 3. Participants perceived the telemedical care mostly as moderately to very helpful (97.5 %, Figure 3A). A majority would like to continue the telemedical care (73.2 %, Figure 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 %, Figure 3C).

Discussion

Quality of life is a major treatment goal for patients with psychiatric disorders [7, 11, 29]. As a secondary outcome, it was proved that 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 of the WHOQOL aspects. An exception was the social relationships domain. The intervention group showed lower values than the control group. This was significant, but close to the significance level of alpha 0.05. The improvement of the other domains and the WHOQOL total quality of life ranged between 2 to 4.1 points, which is moderate but clearly significant. The 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 [30]. 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 [31-33].

As influencing factors age, gender, the education level, social support and the global functioning level (GAF) were revealed. Age is known to be significantly related Quality of lives in patients with schizophrenia [34]. Although age was occasionally significant, the estimates are very low and are all close to zero. Compared to all factors gender (being male) showed the strongest influence with ranges between 2 to 10.3. The results regarding age and male gender are corresponding with other studies [29]. Where education showed significant influence, the observed estimates were moderate. Some authors regard the relationship between socio-demographic factors and quality of life as controversial, weak, or non-existent [35, 36], but some reported significant associations [37, 38]. Our results vary and do not clearly support either view. Social support has a known positive influence on quality of life [36, 39, 40]. This was also significantly verified in our results. The improvement amounted moderate 0.1 to 0.8 points though. To consider also the by the disease caused disability of the subjects the GAF was included in the model. Corresponding to other studies [36, 38, 41], higher GAF levels showed significant better quality of life levels for all domains and the WHOQOL total quality of life. Similarly here, too, the estimates increased by merely moderate values (from 0.1 to 0.5 points).

However, the WHOQOL was proven as an adequate tool for assessing quality of life in different cultures and population groups [42, 43]. 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 [44, 45]. The WHOQOL-BREF is less affected by disease-related factors [17] and has been applied in patients with schizophrenia with good reliability and validity [36, 45], 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, 46]. 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 pragmatic 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 Figure 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 [47, 48], but threshold levels for acceptable dropout-levels are not determined in guidelines yet [48]. 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 [45]. To consider this fact, education was included in the model to control for it.

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.

The duration of the illness is considered as important factor in the literature [35]. In the Tecla study, it was gathered from the patients records by date of first diagnosis. The date was more often not available than available so that it was not possible to include the duration of the illness in to the model.

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.

List Of Abbreviations

CI	Confidence interval
DF	Degree of freedom
eCRF	Electronic Care Report Forms
eHealth	Electronic health
F-SozU	Questionnaire for Social Support
GAF	Global Assessment of Functioning
MAR	Missing at random
MCAR	Missing completely at random
MNAR	Missing not at random
mHealth	Mobile health
MI	Multiple imputation
SD	Standard deviation
Tecla	Study "Post stationary telemedical 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.

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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. KM consulted in the statistical calculations. US conducted the statistical calculations and 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

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

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Figure 1

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

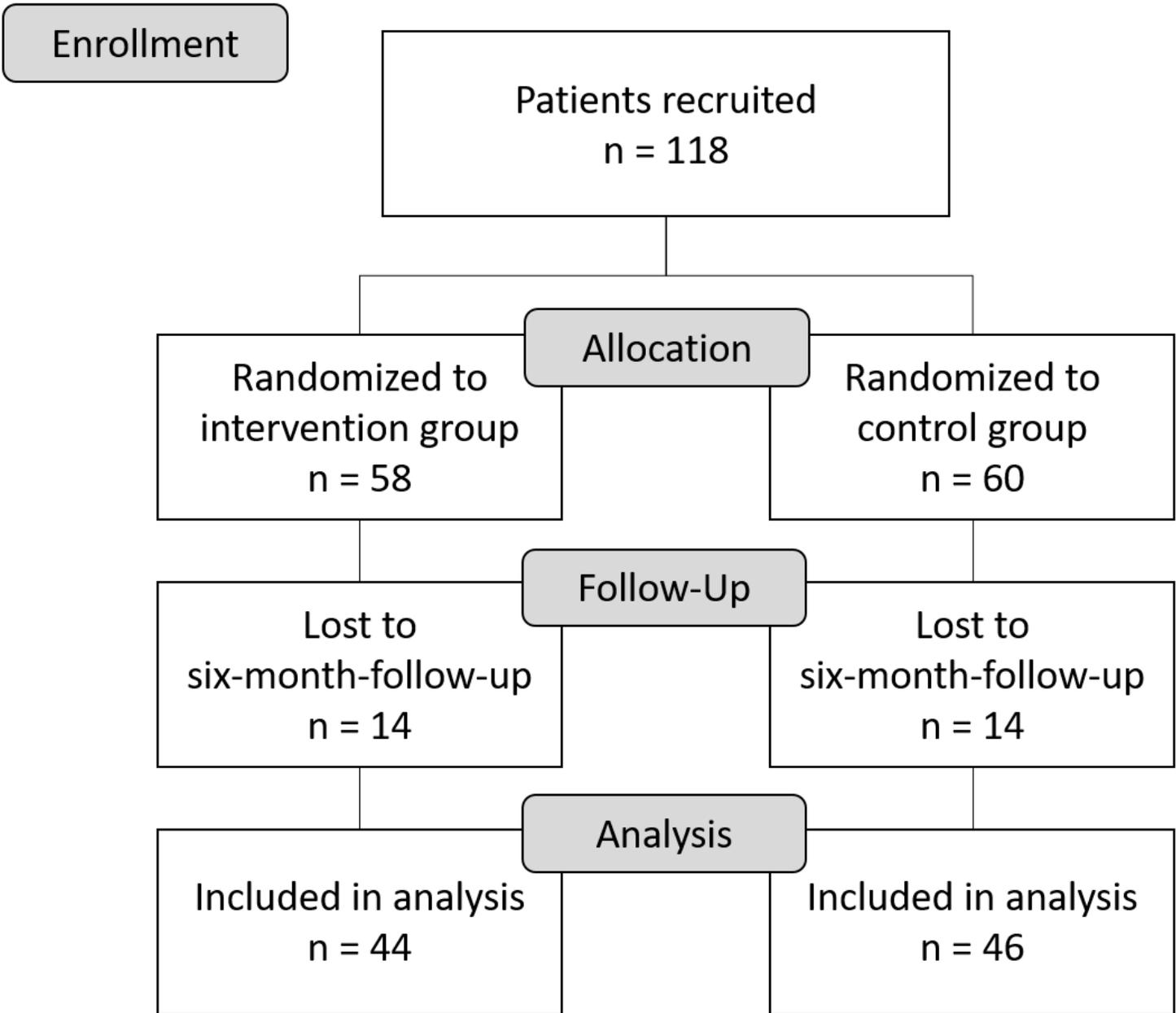


Figure 2

CONSORT flow diagram [28]

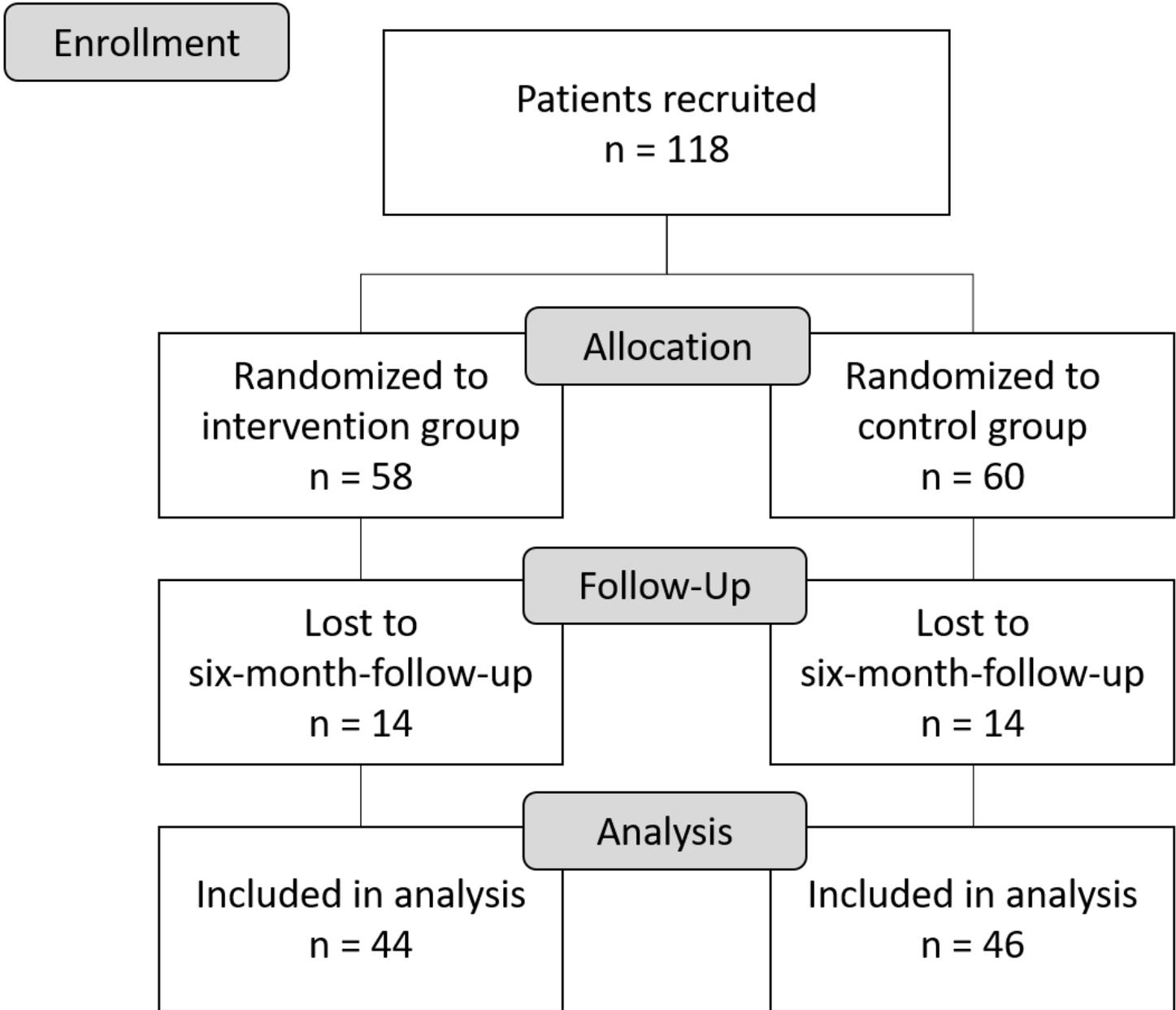


Figure 2

CONSORT flow diagram [28]

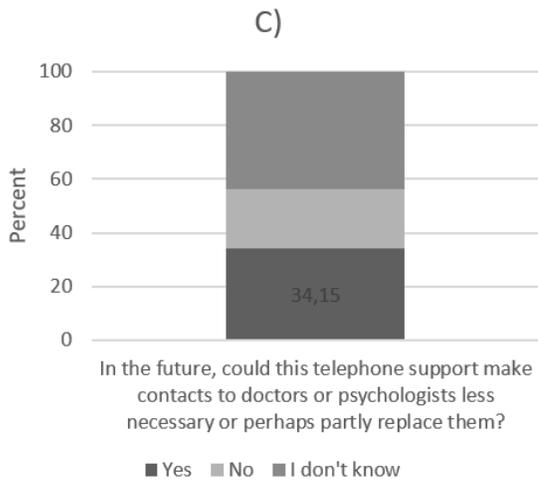
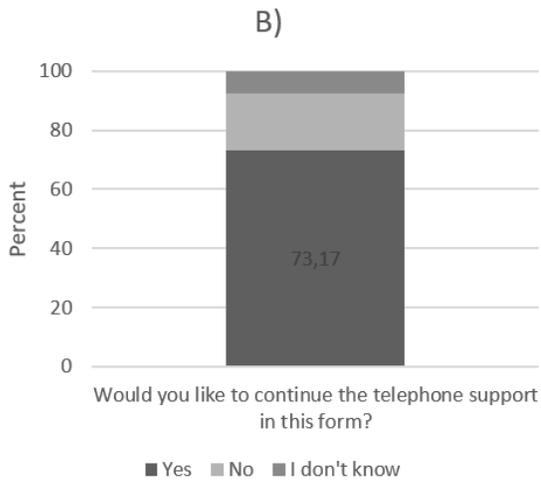
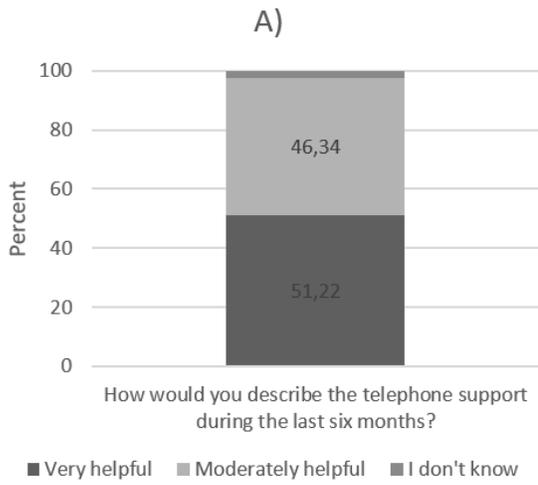


Figure 3

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

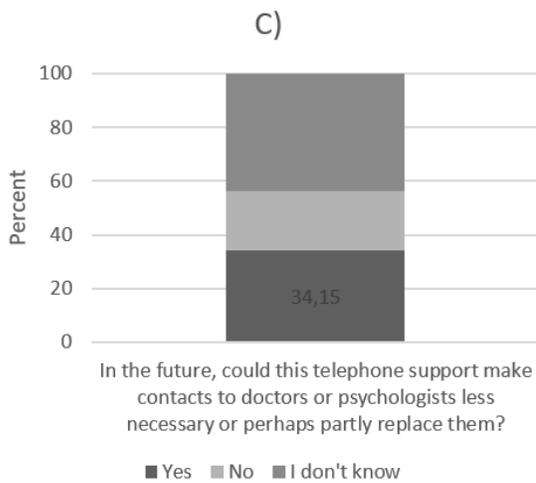
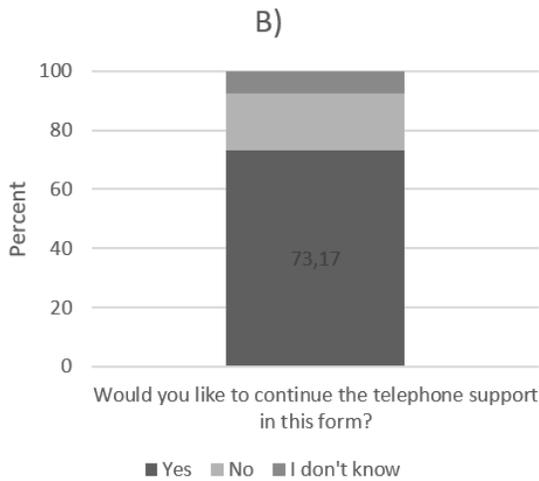
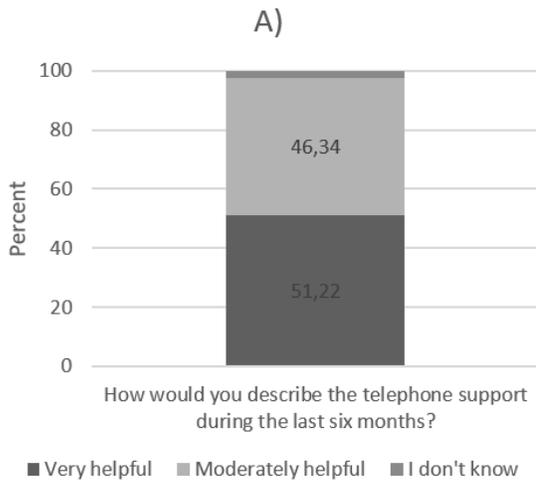


Figure 3

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

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