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Development and psychometric testing of an instrument for measuring social participation of adolescents

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Development and psychometric testing of an instrument for measuring social participation of adolescents

Authors: Tim Bärwalde (a), Britta Gebhard (b), Laura Hoffmann (a, b), Julia Roick (a), Olaf Martin (a), Anna-Lena Neurath (b), Astrid Fink (a)

(a) Institute of Medical Sociology, Martin Luther University Halle-Wittenberg, Halle (Saale), Germany

(b) Faculty of Business and Social Sciences, University of Applied Sciences Nordhausen, Nordhausen, Germany.

Corresponding author:

Astrid Fink
Martin-Luther-University Halle-Wittenberg
Medical Faculty
Institute of Medical Sociology (IMS)
06097 Halle/Saale
Germany
Email: astrid.fink@medizin.uni-halle.de
Phone: +49 345 557 1170

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Development and psychometric testing of an instrument for measuring social participation of adolescents

ABSTRACT

Introduction:

Social participation is an important part of a young person's life. It influences the social experience, social-emotional development, and dimensions of competence experience. This applies to people with or without physical disabilities or chronic diseases. Currently, there is no reliable assessment tool for measuring social participation of adolescents in Germany, even though social participation is a central goal of rehabilitation. The aim of this study is to develop, test and pilot an instrument that assesses social participation for adolescents between the ages of 12 and 17 and to start a psychometric test.

Methods and analysis:

In a sequential mixed-methods study, adolescents with and without physical disabilities or chronic diseases are asked about their experiences with social participation as well as the individual significance of self-determination through semi-structured interviews. The perspective of adolescents is supplemented by focus groups that will be conducted first with experts from social paediatric care and second with legal guardians. Based on this, an assessment instrument will be developed, evaluated and implemented in exemplary social paediatric centres and rehabilitation clinics and psychometrically tested in a pilot study.

Ethics and dissemination:

The study will be conducted in accordance with the principles of the revised Helsinki Declaration (Fortaleza 2013) and the standards of good scientific practice. The data protection is strictly observed on the basis of the legal requirements. The study was approved by the Ethics Review Committee at the Martin-Luther-University Halle-Wittenberg. The results will be presented in several congresses and published in international peer-reviewed journals. The developed assessment instrument can be used in science to identify

1
2
3 32 disadvantaged groups and to compensate for the disadvantages that could impair
4
5 33 development. In practice, the instrument can be used to determine the goals of
6
7 34 rehabilitation together with the adolescents and to evaluate the achievement of these goals.
8
9 35

10 36 **Trial registration number:**

11
12 37 This study has been registered with the German Clinical Trials Register and assigned
13
14 38 DRKS00014739.
15

16 39

17
18 40 **Strengths and limitations of this study**

- 19
20 41 • This mixed-method study will provide profound insights on the theoretical
21
22 42 foundation of the term “social participation” from the point of view of adolescents,
23
24 43 legal guardians and experts.
25
26 44 • It will show the perspective of adolescents with and without physical disabilities and
27
28 45 chronic diseases and, therefore, take several health dimensions into consideration in
29
30 46 order to put a valid assessment tool into practice and research.
31
32 47 • Since this study follows the approach of providing an assessment tool to measure
33
34 48 social participation in adolescents with or without physical disabilities or chronic
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36 49 illnesses, further research and development work is needed to measure social
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38 50 participation in mentally disabled adolescents.
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51 **INTRODUCTION**

52 The introduction of the International Classification of Functioning, Disabilities and Health
53 (ICF) by the World Health Organization (WHO) in 2001¹ led to a change of paradigm in
54 rehabilitative processes and welfare-politics in Germany. Rehabilitative processes and
55 welfare-politics changed from the excluding care approach to an integrative process with
56 preferably unlimited participation of people with disabilities and chronic diseases.² The bio-
57 psychosocial model of the ICF plays an important role in rehabilitation for the recovery of
58 significant improvement in functioning, especially at the level of activities and participation
59 as well as in addressing changes in contextual and environmental factors/barriers, when the
60 participation of a person is endangered or limited.³ The importance of participation as the
61 goal of rehabilitative processes seems undisputed.⁴⁻⁷ The concept of social participation (in
62 the following, only called participation) has increasingly become the focus of science and
63 practice.⁸⁻¹⁰ However, this poses a challenge for science and practice to develop and apply
64 appropriate assessment tools and evaluation-instruments. The German *Law on*
65 *strengthening the participation and self-determination of persons with disabilities* (short
66 form: Federal participation law) requires instruments based on the International
67 Classification of Functioning, Disability and Health for the assessment of individual needs.
68 The instruments should be able to capture restrictions in activities and participation in
69 different areas of life. Participation is particularly important for the development of
70 adolescents. It affects the level of competence experience (e.g., skills), social experience
71 (e.g., relationship experience) and social-emotional development (e.g., self-efficacy, self-
72 concept).¹¹⁻¹³ However, especially for the adolescent group, there are no high-quality
73 assessment tools available in Germany for measuring social participation.¹⁴ For the
74 conception, development and the comparability of assessment tools, a transparent
75 theoretical framework and a consistent understanding of terms are elementary
76 requirements.

78 **The term of social participation**

79 In the International Classification of Functioning, Disabilities and Health for Children and
80 Youth (ICF-CY), participation is described as “involvement in a life situation”¹⁵ which is
81 affected through activities, personality of the adolescent (e.g., motivation) and
82 environmental factors (e.g., family, environmental conditions, legislation).¹⁶ Participation

1
2
3 83 thus includes the social perspective of functioning. At the same time, activity is understood
4
5 84 as the “execution of a task or action by an individual”.¹⁵ Even though in the ICF and the ICF-
6
7 85 CY participation and activity are conceptually differentiated, they are ultimately summarized
8
9 86 in one component, consisting of nine domains.^{14 15 17 18}

10 87 In the distinction between participation and activity, there are different approaches in the
11
12 88 literature. One presumption is that an activity primarily involves a functional aspect of an
13
14 89 action that can be performed without a role performance at the societal level.⁴ Using “a role
15
16 90 performance at the societal level” as a distinguishing criterion should be analysed critically
17
18 91 for adolescents with disabilities or chronic diseases because some activities such as food
19
20 92 consumption frequently take place in interaction with others (e.g., caregivers). The strict
21
22 93 distinction of where an activity is primarily an individual activity is difficult to delineate.¹⁹
23
24 94 Another assumption to distinguish is the view on the complexity of the life situation.²⁰ The
25
26 95 hypothesis where participation differs from activity in terms of complexity seems
27
28 96 reasonable,²⁰ but not distinct enough. It is therefore proposed to differentiate between a
29
30 97 spatial (e.g., school) and temporal (e.g., recurrent daily) component.²¹ In addition to
31
32 98 complexity, participation may also differ from activities by its meaning, and it may be
33
34 99 understood as “sets of organized sequences of activities directed towards a personally or
35
36 100 socially meaningful goal”.²¹ Activities are therefore to be understood as smaller “action
37
38 101 units” out of which sequences of participation are designed. It is important that participation
39
40 102 can be assigned to a rather higher-level goal of action.²¹
41
42 103 Even though four different qualifier options are proposed in the ICF-CY in order to
43
44 104 differentiate between activity and participation,²² there has been no preference or
45
46 105 homogeneity so far.¹⁷ Imms et al. state that there are contemporary descriptions of how
47
48 106 participation can be measured with the help of qualifiers, but in effect, it amounts to activity
49
50 107 competence and not to participation.¹⁸

51 108

51 109 **Theoretical foundation of social participation**

52 110 In rehabilitation science, the concept of participation is predominantly determined by the
53
54 111 ICF-CY. However, this raises the problem that the ICF-CY is based on the framework concept
55
56 112 of the ICF and uses a mutual language, but the ICF itself emerged in a consensus procedure
57
58 113 and lacks a theoretical foundation.²³ Although the ICF-CY model is based on a bio-psycho-

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2
3 114 social understanding of health, it is not sufficiently elaborated. Therefore, a theoretical
4
5 115 inclusion of the concept of participation used here is relatively difficult.

6
7 116 Research suggests that participation is not only the number of activities a child participates
8
9 117 in, or how often they attend that activity (attendance). Additionally, with regard to the
10
11 118 feeling of involvement, prerequisites are observed, indicating it should be personally
12
13 119 meaningful.^{7 24} Even if attendance and involvement are considered set for the concept of
14
15 120 participation, their relationship to each other is not yet completely clarified.¹⁸ To gain a
16
17 121 more holistic view of the construct of participation in the ICF-CY, the introduction of a third
18
19 122 qualifier of the subjective aspects of participation within the activity and participation
20
21 123 domain is discussed.^{7 24 25}

22 124 Participation is considered as a “multidimensional and evolving phenomena with the
23
24 125 interaction of personal and environmental factors occurring over time”.⁷ It is seen as a
25
26 126 process and as a result. For this reason, participation can be considered as both an
27
28 127 independent and a dependent variable in research.^{9 10 18}

29 128 In recent research, Imms et al. have presented a conceptual framework, the family of
30
31 129 participation-related constructs (fPRC)^{18 26}, which are closely related but not identical to
32
33 130 participation. There are intrinsic person-related concepts that include activity competence,
34
35 131 sense of self, and preferences. These concepts influence future participation and are
36
37 132 influenced by past and present participation. In addition, there are extrinsic environment-
38
39 133 related concepts that influence and are influenced by participation. These factors should be
40
41 134 distinguished between environment and context. Context is considered to “be personal,
42
43 135 considered from the perspective of the person participating, and relates to the people,
44
45 136 place, activity, objects, and time in which participation is set”.¹⁸ Whereas “environment is
46
47 137 external, and refers to the broader, objective social and physical structures in which we
48
49 138 live.”¹⁸ The processes of the interactions between these concepts and further distinctions
50
51 139 can be found in Imms et al.¹⁸

52 140 Overall, beyond the simple definition of the term participation in the ICF-CY, profound
53
54 141 consideration is given to the theoretical foundation of the term, and the process of
55
56 142 understanding participation must be continued in science.

57 143

58 144 **Measurement of participation**

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3 145 Some reviews have been published on the analysis of participation assessment tools for
4
5 146 children and adolescents.^{14 17 27-29} In summary, although a large number of assessment
6
7 147 instruments are available, an unqualified recommendation is difficult.^{14 27} This is because
8
9 148 many instruments mix items of activity and participation,^{14 17} no single instrument measures
10
11 149 the whole extent of participation in all life areas,^{14 28} and the quality criteria (on content
12
13 150 validity, internal consistency, reliability and construct validity) are not convincing.^{14 29}
14
15 151 To date, three participation assessment tools have been translated into German language.³⁰⁻
16
17 152 ³² Two of these instruments (“Participation and Environment Measure for Children and
18
19 153 Youth”, PEM-CY³³ and “Children and Adolescent Scale of Participation”, CASP)^{32 34} are used
20
21 154 as an external assessment in which legal guardians (parents or caregivers) assess the
22
23 155 participation of the children or adolescent. This can lead to distortions, in particular due to
24
25 156 the subjective components of participation (meaningfulness). The third and very often used
26
27 157 instrument “Children’s Assessment of Participation and Enjoyment / Preferences for
28
29 158 Activities of Children”, CAPE/PAC³⁵ refers to leisure activities only, does not distinguish
30
31 159 between participation and activity, and only reaches mediocre quality criteria.³¹ Due to the
32
33 160 legal conditions, the German version is not available for scientific or practical use. As a
34
35 161 consequence, there is no reliable and valid instrument for the self-assessment of the
36
37 162 participation of adolescents in German-speaking countries.

163

164 **Aim of this study**

165 This study aims to close parts of the existing gap in participation measurement among
166 adolescents. Instruments for the assessment of participation should be used more often for
167 the planning and evaluation of rehabilitation processes but are hardly available in German
168 speaking practice and research. As part of a sequential mixed-methods study, a participation
169 assessment instrument will be developed for questioning adolescents aged between 12 and
170 17 years.

171

172 **METHODS AND ANALYSIS**

173 **Study design**

174 The study is planned as a sequential mixed-method study. To understand the complex
175 construct of participation and its multiple layers, a qualitative design is first required.
176 Regarding the achievement of the goals outlined above, the exploratory approach in this

1
2
3 177 study offers the opportunity to reconstruct the practice-related experiences and
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5 178 perspectives of the adolescents, their legal guardians (e.g., parents) and interprofessional
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7 179 experts in the paediatric pathways of care. Subjectively perceived needs from the clinical
8
9 180 practice can be explored in order to derive the requirements for an assessment tool. In
10
11 181 terms of counteracting the phenomenon of cognitive dissonance-reduction with its
12
13 182 concomitant adaptive preference mechanism, meaning that goals are adapted to
14
15 183 possibilities, the perspective of adolescents with and without disabilities or chronic diseases
16
17 184 will be fully explored.³⁶

18 185 The study will take place in four phases (figure 1). The first phase will contain data collection
19
20 186 of semi-structured interviews and focus-groups. The analysis of the interviews will be
21
22 187 followed by the development of a survey questionnaire which will be implemented and
23
24 188 evaluated in a pilot study as well as checked psychometrically in this last phase.

25 189 Recruitment into the trial will start in February 2019, and the study is due to finish by
26
27 190 October 2021.

28
29 191
30 192 <Figure 1: Study phases>

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32 193

33 34 194 **Study population/recruitment**

35
36 195 Participating adolescents with physical disabilities or chronic diseases will be recruited via
37
38 196 the education centre for pupils with special needs and the social-paediatric centre (SPC) in
39
40 197 Halle (Saale), Germany. For the recruitment of non-disabled adolescents, four schools (two
41
42 198 in urban regions, two in rural regions) will be approached in order to recruit interview
43
44 199 partners. As part of the recruitment of adolescents, legal guardians should be engaged as
45
46 200 well as participate in focus groups.

47 201 The individual interviews will include adolescents between the ages of 12 and 17, both with
48
49 202 and without disabilities or chronic diseases in the area of physical and motor development.

50
51 203 The interviews will only be conducted when a written consent is available. According to the
52
53 204 theoretical sampling,³⁷ the cases will not be determined at the beginning of the research,
54
55 205 but will be successively recruited in the alternation of collection and development of
56
57 206 theoretical categories, with a following further collection. Depending on the level of the
58
59 207 category it will be decided whether a participant from the urban or rural region is
60
208 interviewed or whether an adolescent with or without disabilities or chronic diseases is

1
2
3 209 interviewed. The recruitment will continue until a theoretical saturation is reached.
4
5 210 Experience from our own and other studies indicate leading approximately 40 interviews, 20
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7 211 with adolescents with disabilities or chronic diseases and 20 with adolescents without
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9 212 disabilities or chronic diseases.³⁸ Adolescents with acute illnesses, with complex cognitive
10
11 213 impairments or without written consent are excluded. The ability to communicate by voice
12
13 214 must be given.

14 215 The national experts for participation are recruited via the “European Association on Early
15
16 216 Childhood Intervention”. Hereby, extensive contacts can be made with different social
17
18 217 paediatric centres and various rehabilitation facilities. The constellation of the focus groups
19
20 218 allows us to generate heterogeneous groups, who work out different experiences and
21
22 219 impressions in their discussions. A group size of six to eight participants has been proven to
23
24 220 be a good group size in focus group discussions with experts.³⁹ The relevant target group will
25
26 221 be better reached by a specific approach rather than by random selection. The selection
27
28 222 strives for a group dynamic which is considered to be beneficial for the research objective of
29
30 223 clarifying the basic understanding of the term (participation), the understanding of the
31
32 224 theoretical construct of social participation of adolescents as well as the addition of the
33
34 225 perspective of the adolescents. The participants of the first phase will be informed about the
35
36 226 second phase of the study. At the same time, the willingness to participate in the second
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38 227 phase of the study (giving feedback to an assessment tool) will be enquired.

39 228

40 229 **Study phase 1: Theoretical discourse**

41 230 *Collecting data of adolescents*

42
43 231 Since the theoretical background and the development of the category system require
44
45 232 detailed knowledge of a person (e.g., the kind of disability) and their situation (e.g., place of
46
47 233 residence), extensive and detailed interviews are conducted which consider the individual
48
49 234 circumstances and provide enough time for the participant.⁴⁰ Semi-structured in-depth
50
51 235 interviews will be conducted, which can take place at the Institute of Medical Sociology, the
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53 236 SPC, at schools or at the home of the participants, with the participants choosing the place
54
55 237 themselves. Topic guides will be developed for the interviews, which contain open questions
56
57 238 and offer areas of discussion that are addressed in the interviews (without specification of a
58
59 239 certain order). The interviews will last a maximum of 60 minutes and are audio-recorded
60
240 with the consent of the participant and completely transcribed afterwards. The literature

1
2
3 241 shows that interviews can be carried out from the age of seven years.^{41 42} Since the
4
5 242 interviews are planned with adolescents from the age of twelve in this research context, the
6
7 243 age-related challenge can be put into perspective because adolescents at this age are able to
8
9 244 have open conversations, both interactively and cognitively as well as verbally. Nevertheless,
10
11 245 during the entire research process, the interviews must be individually adapted to each
12
13 246 adolescent and their individual preconditions. Moreover, the interview guidance of the
14
15 247 researcher must be performed flexibly and carried out preferably by experienced qualitative
16
17 248 interviewers to stimulate narration among shy or reluctant adolescents. For the present
18
19 249 study, it is very important to understand everyday living from the adolescent's point of view
20
21 250 because, especially in regard to opinions, attitudes and the behaviour of adolescents,
22
23 251 interviews with proxies (e.g., interviews with parents or a legal guardian) are insufficient.⁴²
24
25 252 To follow the scientific understanding of Grounded Theory, data collection, preliminary
26
27 253 evaluation and theoretical sampling take place in a reflexive process.³⁷ This procedure is
28
29 254 complemented by theory-oriented coding, constant comparison and writing of memos
30
31 255 throughout the data collection process and beyond.

32

33 257 *Preparation and development of a topic guide*

34 258 Semi-structured topic guides that are developed for individual interviews contain open
35
36 259 questions and provide conversational topics for the talk that are thematised without
37
38 260 predetermining an order.⁴³ This allows the most open conversation technique on sensitive
39
40 261 topics. Taking the conversation dynamics into account, the key questions in the research
41
42 262 process are modified, revised and adapted, and dependent on the study participant.⁴⁰
43
44 263 Despite predetermined problem dimensions, the key questions are designed as open as
45
46 264 possible in order to provide the participants with sufficient space for their representations,
47
48 265 descriptions and arguments. The topic guide is based on existing evidence and aims to
49
50 266 extend previous knowledge. It will be subjected to a pretest.

51 267

52 268 *Analysis of the interviews with adolescents*

53
54 269 The audio-recorded interviews are transcribed and analysed according to Grounded
55
56 270 Theory³⁷ using MAXQDA software: In the first phase of the "open coding", short, incisive and
57
58 271 comparatively abstract concepts (codes) are developed, which characterize the content of
59
60 272 the particular text passage. The second step of the analysis, "axial coding", examines certain

1
2
3 273 categories more intensively by evaluating relationships between this category and other
4
5 274 categories or subcategories. The “selective coding”, as the third analysis step, focuses on the
6
7 275 key categories and prepares the final theory-formation. On the other hand, relationships and
8
9 276 interactions between topics are examined.³⁷ The category scheme is being built up parallel
10
11 277 to the field phase. The collaborative coding is performed by research associates, with a
12
13 278 continuous exchange with principal investigators; additionally, a presentation of the
14
15 279 categories and interpretations in the joint working group “Qualitative Methods” at the
16
17 280 Institute for Medical Sociology is anticipated.

18 281

19 282 *Data collection with the experts and legal guardians*

20
21 283 In the data collection with the experts and the legal guardians, we will use focus group
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23 284 discussions because it is a resource saving method for data collection.³⁹ With that, we
24
25 285 complete the perspective of the adolescents with regard to the perspective of legal
26
27 286 guardians (three groups) and experts (three groups). The focus group is also well-suited for
28
29 287 hypothesis generation⁴⁴ and development of the questionnaire.⁴⁵

30
31 288 In this study, expert opinions are important because the adolescents and their legal
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33 289 guardians can only assess the current situation; however, the experience of how the
34
35 290 disabilities or chronic diseases may develop is the perspective of the experts and
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37 291 practitioners. From a methodological point of view, it is important that respondents are
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39 292 equally or similarly affected by the topic or have expertise on the topic or issue. The
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41 293 individuals themselves are not the focus, but the thematic statements or communications
42
43 294 within the interviewed group are. It is important that the dynamics of the arising group
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45 295 discussions are explicitly included in the analyses because the importance of the interaction,
46
47 296 discourse and group processes for the composition of opinions and the orientation and
48
49 297 meaning of the patterns is essential in this phase.³⁹

50 298

51 299 The topic introductions for the focus groups of the legal guardians are based on the
52
53 300 guideline for the qualitative interviews but are discussed from the perspective of those who
54
55 301 are secondarily affected. Furthermore, aspects from the individual interviews of the
56
57 302 adolescents should be included in the focus groups of the legal guardians. The discussions in
58
59 303 the focus groups are recorded via video technology for in-depth analysis and evaluation.

60 304

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2
3 305 *Analysis of the focus groups with experts and legal guardians*
4

5 306 The results of the focus groups will be compared and supplemented with the current state of
6
7 307 discussions of international literature on the examination of the theoretical construct of
8
9 308 participation. Therefore, the analysis of the focus groups is based on the qualitative thematic
10
11 309 analysis according to Boyatzis.⁴⁶ At the beginning, the analysis will be based on thematically
12
13 310 related passages of description. First, a category system is developed out of the discussion
14
15 311 guide, with the help of which the material is “dismantled” (deductive evaluation strategy). In
16
17 312 the following inductive step, new categories are developed. For this purpose, individual
18
19 313 statements are elaborated and compared through summary, explication and structuring.
20
21 314 Finally, the results are compiled, interpretations are worked out and generalizable
22
23 315 statements are determined. These are brought together with the insights of the data
24
25 316 collections with adolescents and the legal guardians. For the documentation and evaluation
26
27 317 of the data, the software MAXQDA is used.
28

29 318

30 319 **Phase 2: Development of an assessment tool**

31 320 The development of the participation assessment instrument takes place in three steps:
32
33 321 Item generation, qualitative review and cognitive pretest. The collection of items and
34
35 322 required response scales are based on the findings of the qualitative study, as well as
36
37 323 previous theoretical considerations and existing instruments. For the item development, the
38
39 324 categories that are being queried from the interviews are determined. Then, a
40
41 325 determination is made regarding interview results that may have already been adequately
42
43 326 mapped by existing items in other questionnaires. The results of the analysis of the focus
44
45 327 groups are included in the item generation. In addition, the expert opinion regarding the
46
47 328 scaling and dimensioning to be made for the practice is incorporated into the instrument.
48
49 329 Subsequently, questions are constructed for aspects for which there are no suitable items so
50
51 330 far. In the following, the items and response scales are determined methodically. The items
52
53 331 are based as close as possible on the quotes from the interviews to reflect the description,
54
55 332 the quotes and the language used by the group of adolescents. A preliminary version of the
56
57 333 questionnaire will be prepared.

58 334 In a second step, experts (corresponding to the focus groups) and persons affected
59
60 335 (adolescents and their legal guardians) are asked to review the instrument, fill out a
336 questionnaire and send it back to the researchers. The unambiguousness of the item

1
2
3 337 description, explanation of the possible answers as well as the content-related fit,
4
5 338 completeness and missing overlaps are in the foreground. Based on the feedback, a revision
6
7 339 will be made and the version developed here will be included in the cognitive pretest. This
8
9 340 third step is carried out with young people of the target group as a "Think Aloud".⁴⁷ In this
10
11 341 case, people who are filling out the questionnaire are asked to think out loud and to
12
13 342 verbalize their thoughts that lead them to the answer.⁴⁷ With this procedure, hints can be
14
15 343 obtained once again on the most different question problems. The "Think Aloud" is audio-
16
17 344 recorded, additionally recorded in writing and evaluated by means of the thematic analysis
18
19 345 according to Boyatzis.⁴⁶
20 346 The pretested and revised questionnaire will be transferred into the third phase
21
22 347 (implementation).

23 348

25 349 **Phase 3: Implementation into the practical work**

26
27 350 As part of the study, the newly developed questionnaire will be implemented in two practice
28
29 351 areas (SPC and Rehabilitation Clinic for Adolescents). The implementation is carried out with
30
31 352 workshops in the facilities in order to determine the correct usage of the questionnaire.⁴⁸ As
32
33 353 part of these workshops, the first results of the study are presented. The practical
34
35 354 implications are discussed with the participants (doctors, psychologists, physiotherapists,
36
37 355 occupational therapists) and the questionnaires and their usage will be presented.

38 356

40 357 **Phase 4: Pilot study with testing of reliability and validity**

41
42 358 In the pilot study, the questionnaire will be tested in the designated field such as the SPC or
43
44 359 rehabilitation clinics as well as with non-disabled adolescents. For adolescents without
45
46 360 physical disabilities or chronic diseases, schools will be used for access to the adolescents.
47
48 361 For the clinical sample, the staff of the facilities will hand the questionnaire to adolescents in
49
50 362 the facility where they can answer it promptly. The experts in the practice are interviewed
51
52 363 with a short questionnaire regarding the handling of the assessment as well as the utilization
53
54 364 of the results of the questionnaire for further rehabilitation planning. This survey is carried
55
56 365 out on the basis of a quantitative short questionnaire with ready-to-use answering options
57
58 366 in order to allow the highest possible return-rate within the daily routine of a working day of
59
60 367 a specialist.

1
2
3 368 Overall, the pilot study will be designed to deliver a total of 150 responses (100
4
5 369 questionnaires from adolescents in the clinical context and 50 from adolescents without
6
7 370 disabilities or chronic diseases). Therefore, 250 questionnaires will be disseminated. The
8
9 371 response rate among therapists is expected to be lower. Approximately 125 sheets will be
10
11 372 disseminated in order to receive 50 responses from the SPC and rehabilitation clinics.
12
13 373 According to relevant literature, this sample size is appropriate for a pilot study and can also
14
15 374 provide insights in the psychometric testing.⁴⁹⁻⁵¹

16 375 By using the data from the pilot study, various subscales are ascertained by exploratory
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18 376 factor analysis. Cronbach's α is calculated for the different scales as a reliability parameter.
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20 377 The validation testing includes content validity, discriminatory validity and primary construct
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22 378 validity approaches. However, it should be noted that the validity check should be promoted
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24 379 with further assignments and systematic evaluations.

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27 381 **Ethics and dissemination**

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29 382 The study will be conducted in accordance to the principles of the Helsinki Declaration
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31 383 (Fortaleza 2013) and the standards of good scientific practice. The Ethics Review Committee
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33 384 at the Martin-Luther-University Halle-Wittenberg has expressed no dissent concerning this
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35 385 study. All participants will be informed about the meaning, purpose and procedure of the
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37 386 study as well as the handling of the collected data. Written informed consent will be
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39 387 obtained by our research associates from all participants prior to taking part in the study.
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41 388 The participation in the surveys is voluntary and can be withdrawn at any time. In this case,
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43 389 already collected data will be deleted. Non-participation remains without any consequences.
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45 390 All personal identifiers will be pseudonymised. The study is devoted to the development of a
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47 391 participation measurement instrument for adolescents, one of the most urgent care
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49 392 requirements in social paediatrics and rehabilitation. The study will present findings from
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51 393 the point of view of adolescents, their legal guardians and experts on the theoretical
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53 394 foundation of the concept of participation and the demarcation from the concept of
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55 395 activities, and compose a draft for a new participation assessment instrument in German
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57 396 language, which will be piloted and psychometrically tested. The results can be used for
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59 397 further research and development processes and for the practice of rehabilitation planning.
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398 With the knowledge about the theoretical foundation of the participation concept, the
399 present model of the ICF-CY can be extended or concretized.

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For peer review only

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3 401 **Author Contributions** TB wrote the initial draft of this manuscript. BG and AF led the grant
4
5 402 application, and AF wrote the study protocol for the Ethics Review Committee. LH, OM and
6
7 403 JR assisted in the grant application. All authors have read and approved the final version of
8
9 404 this manuscript.

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11
12 406 404636197 (contact via www.dfg.de)
13

14 407 **Competing interests** None declared.
15

16 408 **Ethics approval** The Ethics Review Committee at the Martin-Luther-University Halle-
17
18 409 Wittenberg granted approval.

19 410 **Data statement:** The main data of this study come from interviews with young people who
20
21 411 need special protection. The ethic vote does not allow sharing of the data.
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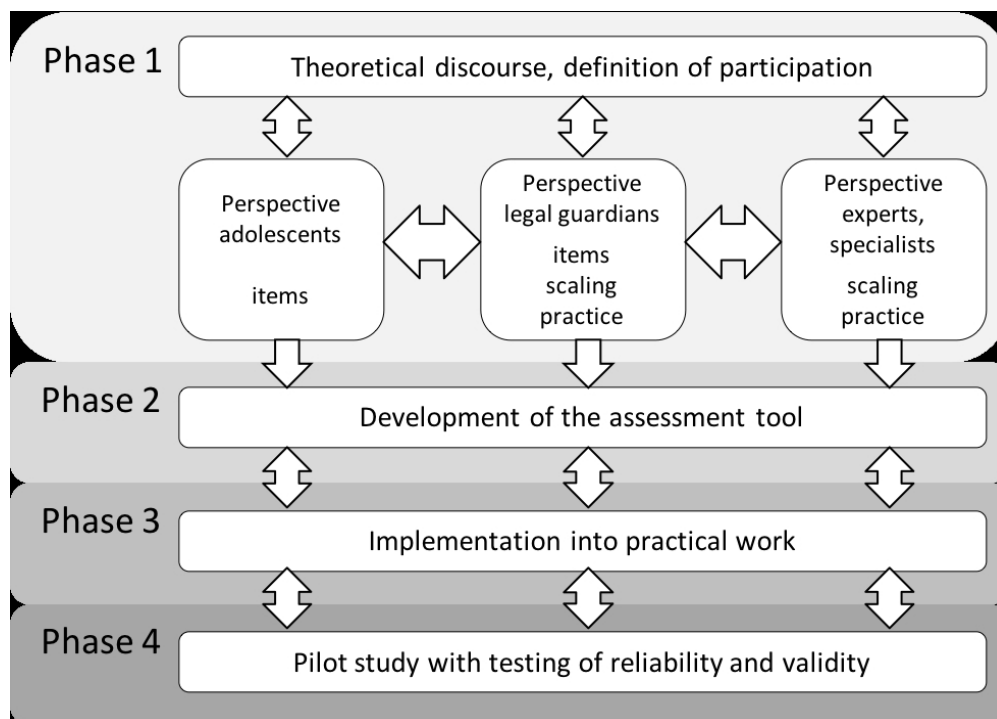
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STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Lines in manuscript
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1-3
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	36-38
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	title page
Funding	4	Sources and types of financial, material, and other support	401-402
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	397-400
	5b	Name and contact information for the trial sponsor	401-402
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	not applicable
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	not applicable
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	51-169 partially not applicable
	6b	Explanation for choice of comparators	143-161 (?)
Objectives	7	Specific objectives or hypotheses	163-169
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	171-188
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	226-252 279-294 353-375
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	199-211
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	not applicable
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	not applicable
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	not applicable
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	not applicable

1 2 3 4 5 6 7 8 9 10 11	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	not applicable
12 13 14 15 16 17 18	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	187-188
19 20 21 22 23 24 25	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	207-210 364-370
26 27 28 29	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	193-198
30	Methods: Assignment of interventions (for controlled trials)			
31 32 33	Allocation:			
34 35 36 37 38 39 40 41 42 43	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	not applicable
44 45 46 47 48 49 50	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	not applicable
51 52 53 54 55 56 57 58 59 60	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	not applicable

1 2 3 4 5 6 7	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	not applicable
8 9 10 11 12		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	not applicable
13 14	Methods: Data collection, management, and analysis			
15 16 17 18 19 20 21 22 23 24 25 26	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	192-375 partially not applicable
27 28 29 30 31 32 33		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	379-385
34 35 36 37 38 39 40 41	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	236-237 266-267 311-314 380-385 405-406
42 43 44 45 46 47	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	not applicable
48 49 50		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	not applicable
51 52 53 54 55 56		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	not applicable
57 58 59 60	Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	not applicable
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	not applicable
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	not applicable
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	not applicable
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	379-381
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	not applicable
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	382-383
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	not applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	381-385
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	403

1 2 3 4 5 6	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	406-407
7 8 9 10	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	not applicable
11 12 13 14 15 16 17 18 19 20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	not applicable
21 22 23 24		31b	Authorship eligibility guidelines and any intended use of professional writers	not applicable
25 26 27 28		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	not applicable
29 30	Appendices			
31 32 33 34 35	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	not applicable
36 37 38 39 40	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	not applicable

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*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

BMJ Open

Development and psychometric testing of an instrument for measuring social participation of adolescents. Study protocol of a prospective mixed-methods study.

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Primary Subject Heading:	Sociology
Secondary Subject Heading:	Paediatrics
Keywords:	physical disabilities, assessment instrument, adolescents, social participation

SCHOLARONE™
Manuscripts

Development and psychometric testing of an instrument for measuring social participation of adolescents. Study protocol of a prospective mixed methods study.

Authors: Tim Baerwalde (a), Britta Gebhard (b), Laura Hoffmann (a, b), Julia Roick (a), Olaf Martin (a), Anna-Lena Neurath (b), Astrid Fink (a)

(a) Institute of Medical Sociology, Martin Luther University Halle-Wittenberg, Halle (Saale), Germany

(b) Faculty of Business and Social Sciences, University of Applied Sciences Nordhausen, Nordhausen, Germany.

Corresponding author:

Astrid Fink

Martin-Luther-University Halle-Wittenberg

Medical Faculty

Institute of Medical Sociology (IMS)

06097 Halle/Saale

Germany

Email: astrid.fink@medizin.uni-halle.de

Phone: +49 345 557 1170

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Development and psychometric testing of an instrument for measuring social participation of adolescents. Study protocol of a prospective mixed methods study.

ABSTRACT

Introduction:

Social participation is an important part of a young person's life. It influences the social experience, social-emotional development, and dimensions of competence experience. This applies to people with or without physical disabilities or chronic diseases. Currently, there is no reliable assessment tool for measuring social participation of adolescents in Germany, even though social participation is a central goal of rehabilitation. The aim of this study is to develop, test and pilot an instrument that assesses social participation for adolescents between the ages of 12 and 17 and to start a psychometric test.

Methods and analysis:

In a sequential mixed-methods study, adolescents with and without physical disabilities or chronic diseases are asked about their experiences with social participation as well as the individual significance of self-determination through semi-structured interviews. The perspective of adolescents is supplemented by focus groups that will be conducted first with experts from social paediatric care and second with legal guardians. Based on this, an assessment instrument will be developed, evaluated and implemented in exemplary social paediatric centres and rehabilitation clinics and psychometrically tested in a pilot study.

Ethics and dissemination:

The study will be conducted in accordance with the principles of the revised Helsinki Declaration. The study was approved by the Ethics Review Committee at the Martin-Luther-University Halle-Wittenberg. The developed assessment instrument can be used in science to identify disadvantaged groups and to compensate for the disadvantages that could impair development. For this purpose, the results will be presented at scientific conferences and

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3 32 published in international peer-reviewed journals. In practice, the instrument can be used
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5 33 to determine the goals of rehabilitation together with the adolescents and to evaluate the
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7 34 achievement of these goals. For this, implementation workshops and further training will be
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9 35 organised and carried out in children's rehabilitation clinics and social paediatric centres.
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12 37 **Trial registration number:**

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14 38 This study has been registered with the German Clinical Trials Register and assigned
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16 39 DRKS00014739.
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19 41 **Strengths and limitations of this study**

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21 42
- 22 43 • This mixed-method study will provide profound insights on the theoretical
23 44 foundation of the term “social participation” from the point of view of adolescents,
24 45 legal guardians and experts.
 - 25 46 • It will show the perspective of adolescents with and without physical disabilities and
26 47 chronic diseases and, therefore, take several health dimensions into consideration in
27 48 order to put a valid assessment tool into practice and research.
 - 28 49 • Since this study follows the approach of providing an assessment tool to measure
29 50 social participation in adolescents with or without physical disabilities or chronic
30 51 illnesses, further research and development work is needed to measure social
31 52 participation in mentally disabled adolescents.
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52 **INTRODUCTION**

53 The introduction of the International Classification of Functioning, Disabilities and Health (ICF)
54 by the World Health Organization (WHO) in 2001¹ led to a change of paradigm in rehabilitative
55 processes and welfare-politics in Germany. Rehabilitative processes and welfare-politics
56 changed from the excluding care approach to an integrative process with preferably unlimited
57 participation of people with disabilities and chronic diseases.² The bio-psychosocial model of
58 the ICF plays an important role in rehabilitation for the recovery of significant improvement
59 in functioning, especially at the level of activities and participation as well as in addressing
60 changes in contextual and environmental factors/barriers, when the participation of a person
61 is endangered or limited.³ The importance of participation as the goal of rehabilitative
62 processes seems undisputed.⁴⁻⁷ The concept of social participation (in the following, only
63 called participation) has increasingly become the focus of science and practice.⁸⁻¹⁰ However,
64 this poses a challenge for science and practice to develop and apply appropriate assessment
65 tools and evaluation-instruments. The German *Law on strengthening the participation and*
66 *self-determination of persons with disabilities* (short form: Federal participation law) requires
67 instruments based on the International Classification of Functioning, Disability and Health for
68 the assessment of individual needs. The instruments should be able to capture restrictions in
69 activities and participation in different areas of life. Participation is particularly important for
70 the development of adolescents. It affects the level of competence experience (e.g., skills),
71 social experience (e.g., relationship experience) and social-emotional development (e.g., self-
72 efficacy, self-concept).¹¹⁻¹³ However, especially for the adolescent group, there are no high-
73 quality assessment tools available in Germany for measuring social participation.¹⁴ For the
74 conception, development and the comparability of assessment tools, a transparent
75 theoretical framework and a consistent understanding of terms are elementary requirements.

76

77 **The term of social participation**

78 In the International Classification of Functioning, Disabilities and Health for Children and Youth
79 (ICF-CY), participation is described as “involvement in a life situation”¹⁵ which is affected
80 through activities, personality of the adolescent (e.g., motivation) and environmental factors
81 (e.g., family, environmental conditions, legislation).¹⁶ Participation thus includes the social
82 perspective of functioning. At the same time, activity is understood as the “execution of a task
83 or action by an individual”.¹⁵ Even though in the ICF and the ICF-CY participation and activity

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3 84 are conceptually differentiated, they are ultimately summarized in one component, consisting
4
5 85 of nine domains.^{14 15 17 18}

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7 86 In the distinction between participation and activity, there are different approaches in the
8
9 87 literature. One presumption is that an activity primarily involves a functional aspect of an
10
11 88 action that can be performed without a role performance at the societal level.⁴ Using “a role
12
13 89 performance at the societal level” as a distinguishing criterion should be analysed critically for
14
15 90 adolescents with disabilities or chronic diseases because some activities such as food
16
17 91 consumption frequently take place in interaction with others (e.g., caregivers). The strict
18
19 92 distinction of where an activity is primarily an individual activity is difficult to delineate.¹⁹
20
21 93 Another assumption to distinguish is the view on the complexity of the life situation.²⁰ The
22
23 94 hypothesis where participation differs from activity in terms of complexity seems
24
25 95 reasonable,²⁰ but not distinct enough. It is therefore proposed to differentiate between a
26
27 96 spatial (e.g., school) and temporal (e.g., recurrent daily) component.²¹ In addition to
28
29 97 complexity, participation may also differ from activities by its meaning, and it may be
30
31 98 understood as “sets of organized sequences of activities directed towards a personally or
32
33 99 socially meaningful goal”.²¹ Activities are therefore to be understood as smaller “action units”
34
35 100 out of which sequences of participation are designed. It is important that participation can be
36
37 101 assigned to a rather higher-level goal of action.²¹
38
39 102 Even though four different qualifier options are proposed in the ICF-CY in order to
40
41 103 differentiate between activity and participation,²² there has been no preference or
42
43 104 homogeneity so far.¹⁷ Imms et al. state that there are contemporary descriptions of how
44
45 105 participation can be measured with the help of qualifiers, but in effect, it amounts to activity
46
47 106 competence and not to participation.¹⁸

48

108 **Theoretical foundation of social participation**

49 109 In rehabilitation science, the concept of participation is predominantly determined by the ICF-
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51 110 CY. However, this raises the problem that the ICF-CY is based on the framework concept of
52
53 111 the ICF and uses a mutual language, but the ICF itself emerged in a consensus procedure and
54
55 112 lacks a theoretical foundation.²³ Although the ICF-CY model is based on a bio-psycho-social
56
57 113 understanding of health, it is not sufficiently elaborated. Therefore, a theoretical inclusion of
58
59 114 the concept of participation used here is relatively difficult.

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3 115 Research suggests that participation is not only the number of activities a child participates in,
4
5 116 or how often they attend that activity (attendance). Additionally, with regard to the feeling of
6
7 117 involvement, prerequisites are observed, indicating it should be personally meaningful.^{7 24}
8
9 118 Even if attendance and involvement are considered set for the concept of participation, their
10
11 119 relationship to each other is not yet completely clarified.¹⁸ To gain a more holistic view of the
12
13 120 construct of participation in the ICF-CY, the introduction of a third qualifier of the subjective
14
15 121 aspects of participation within the activity and participation domain is discussed.^{7 24 25}
16
17 122 Participation is considered as a “multidimensional and evolving phenomena with the
18
19 123 interaction of personal and environmental factors occurring over time”.⁷ It is seen as a process
20
21 124 and as a result. For this reason, participation can be considered as both an independent and
22
23 125 a dependent variable in research.^{9 10 18}
24
25 126 In recent research, Imms et al. have presented a conceptual framework, the family of
26
27 127 participation-related constructs (fPRC)^{18 26}, which are closely related but not identical to
28
29 128 participation. There are intrinsic person-related concepts that include activity competence,
30
31 129 sense of self, and preferences. These concepts influence future participation and are
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33 130 influenced by past and present participation. In addition, there are extrinsic environment-
34
35 131 related concepts that influence and are influenced by participation. These factors should be
36
37 132 distinguished between environment and context. Context is considered to “be personal,
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39 133 considered from the perspective of the person participating, and relates to the people, place,
40
41 134 activity, objects, and time in which participation is set”.¹⁸ Whereas “environment is external,
42
43 135 and refers to the broader, objective social and physical structures in which we live.”¹⁸ The
44
45 136 processes of the interactions between these concepts and further distinctions can be found
46
47 137 in Imms et al.¹⁸
48
49 138 Overall, beyond the simple definition of the term participation in the ICF-CY, profound
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51 139 consideration is given to the theoretical foundation of the term, and the process of
52
53 140 understanding participation must be continued in science.

141

142 **Measurement of participation**

143 Some reviews have been published on the analysis of participation assessment tools for
144 children and adolescents.^{14 17 27-29} In summary, although a large number of assessment
145 instruments are available, an unqualified recommendation is difficult.^{14 27} This is because
146 many instruments mix items of activity and participation,^{14 17} no single instrument measures

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3 147 the whole extent of participation in all life areas,^{14 28} and the quality criteria (on content
4
5 148 validity, internal consistency, reliability and construct validity) are not convincing.^{14 29}
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7 149 To date, three participation assessment tools have been translated into German language.³⁰⁻
8
9 150 ³² Two of these instruments (“Participation and Environment Measure for Children and
10
11 151 Youth”, PEM-CY³³ and “Children and Adolescent Scale of Participation”, CASP)^{32 34} are used as
12
13 152 an external assessment in which legal guardians (parents or caregivers) assess the
14
15 153 participation of the children or adolescent. This can lead to distortions, in particular due to
16
17 154 the subjective components of participation (meaningfulness). The third and very often used
18
19 155 instrument “Children’s Assessment of Participation and Enjoyment / Preferences for Activities
20
21 156 of Children”, CAPE/PAC³⁵ refers to leisure activities only, does not distinguish between
22
23 157 participation and activity, and only reaches mediocre quality criteria.³¹ Due to the legal
24
25 158 conditions, the German version is not available for scientific or practical use. As a
26
27 159 consequence, there is no reliable and valid instrument for the self-assessment of the
28
29 160 participation of adolescents in German-speaking countries.
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161

162 **Aim of this study**

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32 163 This study aims to close parts of the existing gap in participation measurement among
33
34 164 adolescents. Instruments for the assessment of participation should be used more often for
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36 165 the planning and evaluation of rehabilitation processes but are hardly available in German
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38 166 speaking practice and research. As part of a sequential mixed-methods study, a participation
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40 167 assessment instrument will be developed for questioning adolescents aged between 12 and
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42 168 17 years.
43

169

170 **METHODS AND ANALYSIS**

171 **Study design**

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48 172 The study is planned as a sequential mixed-method study. To understand the complex
49
50 173 construct of participation and its multiple layers, a qualitative design is first required.
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52 174 Regarding the achievement of the goals outlined above, the exploratory approach in this study
53
54 175 offers the opportunity to reconstruct the practice-related experiences and perspectives of the
55
56 176 adolescents, their legal guardians (e.g., parents) and interprofessional experts in the
57
58 177 paediatric pathways of care. Subjectively perceived needs from the clinical practice can be
59
60 178 explored in order to derive the requirements for an assessment tool. In terms of counteracting

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3 179 the phenomenon of cognitive dissonance-reduction with its concomitant adaptive preference
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5 180 mechanism, meaning that goals are adapted to possibilities, the perspective of adolescents
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7 181 with and without disabilities or chronic diseases will be fully explored.³⁶

8
9 182 The study will take place in four phases (figure 1). The first phase will contain data collection
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11 183 of semi-structured interviews and focus-groups. The analysis of the interviews will be followed
12
13 184 by the development of a survey questionnaire which will be implemented and evaluated in a
14
15 185 pilot study as well as checked psychometrically in this last phase.

16 186 Recruitment into the trial will start in February 2019, and the study is due to finish by October
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18 187 2021.

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20 188

21 189 <Figure 1: Study phases>

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23 190

24 25 191 **Patient and Public Involvement**

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27 192 Some years ago, the two principle investigators (AF and BG) worked with existing assessment
28
29 193 instruments to record social participation.^{14 31} By working with the participants, they
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31 194 identified the limitations of the existing instruments and identified the need to develop a new
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33 195 instrument. This finding is based, besides the literature, on the priorities, experiences and
34
35 196 preferences of the participants at that time and led to the developed question. The study
36
37 197 design is a classic design for the development of new assessment instruments. The principles
38
39 198 of good scientific practice were the guiding principles. The target group of the study, young
40
41 199 people between the ages of 12 and 17, were not included in the development of the design.
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43 200 The open approach of the qualitative part of the study offers opportunities for adaptation
44
45 201 based on the participants' preferences and experiences in recruitment and conduction of the
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47 202 study. As the instrument is more intended to support practice and research, the interest of
48
49 203 individual participants may be relatively low. However, since participation in research may be
50
51 204 an exciting experience for young people and their legal guardians, ways of reflecting results
52
53 205 are being prepared. The results of the study will be sent to the participants individually on
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55 206 request, in addition the settings of the participants (schools, social-paediatric centres etc.) will
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57 207 be informed and, if desired, information events on the results will be arranged. The results
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59 208 will be published in scientific journals. It is also planned to distribute the results and the final
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209 version of the instrument e.g. to rehabilitation centres and social paediatric centres for free.

210

211 **Study population/recruitment**

212 Participating adolescents with physical disabilities or chronic diseases will be recruited via the
213 education centre for pupils with special needs and the social-paediatric centre (SPC) in Halle
214 (Saale), Germany. For the recruitment of non-disabled adolescents, four schools (two in urban
215 regions, two in rural regions) will be approached in order to recruit interview partners. As part
216 of the recruitment of adolescents, legal guardians should be engaged as well as participate in
217 focus groups.

218 The individual interviews will include adolescents between the ages of 12 and 17, both with
219 and without disabilities or chronic diseases in the area of physical and motor development.

220 The interviews will only be conducted when a written consent is available. According to the
221 theoretical sampling,³⁷ the cases will not be determined at the beginning of the research, but
222 will be successively recruited in the alternation of collection and development of theoretical
223 categories, with a following further collection. Depending on the level of the category it will
224 be decided whether a participant from the urban or rural region is interviewed or whether an
225 adolescent with or without disabilities or chronic diseases is interviewed. The recruitment will
226 continue until a theoretical saturation is reached. Experience from our own and other studies
227 indicate leading approximately 40 interviews, 20 with adolescents with disabilities or chronic
228 diseases and 20 with adolescents without disabilities or chronic diseases.³⁸ Adolescents with
229 acute illnesses, with complex cognitive impairments or without written consent are excluded.
230 The ability to communicate by voice must be given.

231 The national experts for participation are recruited via the “European Association on Early
232 Childhood Intervention”. Hereby, extensive contacts can be made with different social
233 paediatric centres and various rehabilitation facilities. The constellation of the focus groups
234 allows us to generate heterogeneous groups, who work out different experiences and
235 impressions in their discussions. A group size of six to eight participants has been proven to
236 be a good group size in focus group discussions with experts.³⁹ The relevant target group will
237 be better reached by a specific approach rather than by random selection. The selection
238 strives for a group dynamic which is considered to be beneficial for the research objective of
239 clarifying the basic understanding of the term (participation), the understanding of the
240 theoretical construct of social participation of adolescents as well as the addition of the
241 perspective of the adolescents. The participants of the first phase will be informed about the

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3 242 second phase of the study. At the same time, the willingness to participate in the second phase
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5 243 of the study (giving feedback to an assessment tool) will be enquired.
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9 245 **Study phase 1: Theoretical discourse**

10 246 *Collecting data of adolescents*

11
12 247 Since the theoretical background and the development of the category system require
13
14 248 detailed knowledge of a person (e.g., the kind of disability) and their situation (e.g., place of
15
16 249 residence), extensive and detailed interviews are conducted which consider the individual
17
18 250 circumstances and provide enough time for the participant.⁴⁰ Semi-structured in-depth
19
20 251 interviews will be conducted, which can take place at the Institute of Medical Sociology, the
21
22 252 SPC, at schools or at the home of the participants, with the participants choosing the place
23
24 253 themselves. Topic guides will be developed for the interviews, which contain open questions
25
26 254 and offer areas of discussion that are addressed in the interviews (without specification of a
27
28 255 certain order). The interviews will last a maximum of 60 minutes and are audio-recorded with
29
30 256 the consent of the participant and completely transcribed afterwards. The literature shows
31
32 257 that interviews can be carried out from the age of seven years.^{41 42} Since the interviews are
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34 258 planned with adolescents from the age of twelve in this research context, the age-related
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36 259 challenge can be put into perspective because adolescents at this age are able to have open
37
38 260 conversations, both interactively and cognitively as well as verbally. Nevertheless, during the
39
40 261 entire research process, the interviews must be individually adapted to each adolescent and
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42 262 their individual preconditions. Moreover, the interview guidance of the researcher must be
43
44 263 performed flexibly and carried out preferably by experienced qualitative interviewers to
45
46 264 stimulate narration among shy or reluctant adolescents. For the present study, it is very
47
48 265 important to understand everyday living from the adolescent's point of view because,
49
50 266 especially in regard to opinions, attitudes and the behaviour of adolescents, interviews with
51
52 267 proxies (e.g., interviews with parents or a legal guardian) are insufficient.⁴²

53
54 268 To follow the scientific understanding of Grounded Theory, data collection, preliminary
55
56 269 evaluation and theoretical sampling take place in a reflexive process.³⁷ This procedure is
57
58 270 complemented by theory-oriented coding, constant comparison and writing of memos
59
60 271 throughout the data collection process and beyond.

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59
60 273 *Preparation and development of a topic guide*

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3 274 Semi-structured topic guides that are developed for individual interviews contain open
4
5 275 questions and provide conversational topics for the talk that are thematised without
6
7 276 predetermining an order.⁴³ This allows the most open conversation technique on sensitive
8
9 277 topics. Taking the conversation dynamics into account, the key questions in the research
10
11 278 process are modified, revised and adapted, and dependent on the study participant.⁴⁰ Despite
12
13 279 predetermined problem dimensions, the key questions are designed as open as possible in
14
15 280 order to provide the participants with sufficient space for their representations, descriptions
16
17 281 and arguments. The topic guide is based on existing evidence and aims to extend previous
18
19 282 knowledge. It will be subjected to a pretest.
20

283

284 *Analysis of the interviews with adolescents*

285 The audio-recorded interviews are transcribed and analysed according to Grounded Theory³⁷
286 using MAXQDA software: In the first phase of the “open coding”, short, incisive and
287 comparatively abstract concepts (codes) are developed, which characterize the content of the
288 particular text passage. The second step of the analysis, “axial coding”, examines certain
289 categories more intensively by evaluating relationships between this category and other
290 categories or subcategories. The “selective coding”, as the third analysis step, focuses on the
291 key categories and prepares the final theory-formation. On the other hand, relationships and
292 interactions between topics are examined.³⁷ The category scheme is being built up parallel to
293 the field phase. The collaborative coding is performed by research associates, with a
294 continuous exchange with principal investigators; additionally, a presentation of the
295 categories and interpretations in the joint working group “Qualitative Methods” at the
296 Institute for Medical Sociology is anticipated.

297

298 *Data collection with the experts and legal guardians*

299 In the data collection with the experts and the legal guardians, we will use focus group
300 discussions because it is a resource saving method for data collection.³⁹ With that, we
301 complete the perspective of the adolescents with regard to the perspective of legal guardians
302 (three groups) and experts (three groups). The focus group is also well-suited for hypothesis
303 generation⁴⁴ and development of the questionnaire.⁴⁵

304 In this study, expert opinions are important because the adolescents and their legal guardians
305 can only assess the current situation; however, the experience of how the disabilities or

1
2
3 306 chronic diseases may develop is the perspective of the experts and practitioners. From a
4
5 307 methodological point of view, it is important that respondents are equally or similarly affected
6
7 308 by the topic or have expertise on the topic or issue. The individuals themselves are not the
8
9 309 focus, but the thematic statements or communications within the interviewed group are. It is
10
11 310 important that the dynamics of the arising group discussions are explicitly included in the
12
13 311 analyses because the importance of the interaction, discourse and group processes for the
14
15 312 composition of opinions and the orientation and meaning of the patterns is essential in this
16
17 313 phase.³⁹

18 314

19
20 315 The topic introductions for the focus groups of the legal guardians are based on the guideline
21
22 316 for the qualitative interviews but are discussed from the perspective of those who are
23
24 317 secondarily affected. Furthermore, aspects from the individual interviews of the adolescents
25
26 318 should be included in the focus groups of the legal guardians. The discussions in the focus
27
28 319 groups are recorded via video technology for in-depth analysis and evaluation.

29 320

30 321 *Analysis of the focus groups with experts and legal guardians*

31
32 322 The results of the focus groups will be compared and supplemented with the current state of
33
34 323 discussions of international literature on the examination of the theoretical construct of
35
36 324 participation. Therefore, the analysis of the focus groups is based on the qualitative thematic
37
38 325 analysis according to Boyatzis.⁴⁶ At the beginning, the analysis will be based on thematically
39
40 326 related passages of description. First, a category system is developed out of the discussion
41
42 327 guide, with the help of which the material is “dismantled” (deductive evaluation strategy). In
43
44 328 the following inductive step, new categories are developed. For this purpose, individual
45
46 329 statements are elaborated and compared through summary, explication and structuring.

47 330 Finally, the results are compiled, interpretations are worked out and generalizable statements
48
49 331 are determined. These are brought together with the insights of the data collections with
50
51 332 adolescents and the legal guardians. For the documentation and evaluation of the data, the
52
53 333 software MAXQDA is used.

54 334

55 335 **Phase 2: Development of an assessment tool**

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58 336 The development of the participation assessment instrument takes place in three steps: Item
59
60 337 generation, qualitative review and cognitive pretest. The collection of items and required

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2
3 338 response scales are based on the findings of the qualitative study, as well as previous
4
5 339 theoretical considerations and existing instruments. For the item development, the categories
6
7 340 that are being queried from the interviews are determined. Then, a determination is made
8
9 341 regarding interview results that may have already been adequately mapped by existing items
10
11 342 in other questionnaires. The results of the analysis of the focus groups are included in the item
12
13 343 generation. In addition, the expert opinion regarding the scaling and dimensioning to be made
14
15 344 for the practice is incorporated into the instrument. Subsequently, questions are constructed
16
17 345 for aspects for which there are no suitable items so far. In the following, the items and
18
19 346 response scales are determined methodically. The items are based as close as possible on the
20
21 347 quotes from the interviews to reflect the description, the quotes and the language used by
22
23 348 the group of adolescents. A preliminary version of the questionnaire will be prepared.

24
25 349 In a second step, experts (corresponding to the focus groups) and persons affected
26
27 350 (adolescents and their legal guardians) are asked to review the instrument, fill out a
28
29 351 questionnaire and send it back to the researchers. The unambiguousness of the item
30
31 352 description, explanation of the possible answers as well as the content-related fit,
32
33 353 completeness and missing overlaps are in the foreground. Based on the feedback, a revision
34
35 354 will be made and the version developed here will be included in the cognitive pretest. This
36
37 355 third step is carried out with young people of the target group as a "Think Aloud".⁴⁷ In this
38
39 356 case, people who are filling out the questionnaire are asked to think out loud and to verbalize
40
41 357 their thoughts that lead them to the answer.⁴⁷ With this procedure, hints can be obtained
42
43 358 once again on the most different question problems. The "Think Aloud" is audio-recorded,
44
45 359 additionally recorded in writing and evaluated by means of the thematic analysis according to
46
47 360 Boyatzis.⁴⁶

48
49 361 The pretested and revised questionnaire will be transferred into the third phase
50
51 362 (implementation).

52
53 363

54 364 **Phase 3: Implementation into the practical work**

55 365 As part of the study, the newly developed questionnaire will be implemented in two practice
56
57 366 areas (SPC and Rehabilitation Clinic for Adolescents). The implementation is carried out with
58
59 367 workshops in the facilities in order to determine the correct usage of the questionnaire.⁴⁸ As
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368 part of these workshops, the first results of the study are presented. The practical implications

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2
3 369 are discussed with the participants (doctors, psychologists, physiotherapists, occupational
4 370 therapists) and the questionnaires and their usage will be presented.

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8
9 372 **Phase 4: Pilot study with testing of reliability and validity**

10 373 In the pilot study, the questionnaire will be tested in the designated field such as the SPC or
11 374 rehabilitation clinics as well as with non-disabled adolescents. For adolescents without
12 375 physical disabilities or chronic diseases, schools will be used for access to the adolescents.

13
14 376 For the clinical sample, the staff of the facilities will hand the questionnaire to adolescents in
15
16 377 the facility where they can answer it promptly. The experts in the practice are interviewed
17
18 378 with a short questionnaire regarding the handling of the assessment as well as the utilization
19
20 379 of the results of the questionnaire for further rehabilitation planning. This survey is carried out
21
22 380 on the basis of a quantitative short questionnaire with ready-to-use answering options in
23
24 381 order to allow the highest possible return-rate within the daily routine of a working day of a
25
26 382 specialist.

27
28
29 383 Overall, the pilot study will be designed to deliver a total of 150 responses (100 questionnaires
30
31 384 from adolescents in the clinical context and 50 from adolescents without disabilities or chronic
32
33 385 diseases). Therefore, 250 questionnaires will be disseminated. The response rate among
34
35 386 therapists is expected to be lower. Approximately 125 sheets will be disseminated in order to
36
37 387 receive 50 responses from the SPC and rehabilitation clinics. According to relevant literature,
38
39 388 this sample size is appropriate for a pilot study and can also provide insights in the
40
41 389 psychometric testing.⁴⁹⁻⁵¹

42 390 By using the data from the pilot study, various subscales are ascertained by exploratory factor
43
44 391 analysis. Cronbach's α is calculated for the different scales as a reliability parameter. The
45
46 392 validation testing includes content validity, discriminatory validity and primary construct
47
48 393 validity approaches. However, it should be noted that the validity check should be promoted
49
50 394 with further assignments and systematic evaluations.

51 395

52 396 **Ethics and dissemination**

53
54 397 The study will be conducted in accordance to the principles of the Helsinki Declaration
55
56 398 (Fortaleza 2013) and the standards of good scientific practice. The Ethics Review Committee
57
58 399 at the Martin-Luther-University Halle-Wittenberg has expressed no dissent concerning this
59
60 400 study. All participants will be informed about the meaning, purpose and procedure of the

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2
3 401 study as well as the handling of the collected data. Written informed consent will be obtained
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5 402 by our research associates from all participants prior to taking part in the study. The
6
7 403 participation in the surveys is voluntary and can be withdrawn at any time. In this case, already
8
9 404 collected data will be deleted. Non-participation remains without any consequences. All
10
11 405 personal identifiers will be pseudonymised. The study is devoted to the development of a
12
13 406 participation measurement instrument for adolescents, one of the most urgent care
14
15 407 requirements in social paediatrics and rehabilitation. The study will present findings from the
16
17 408 point of view of adolescents, their legal guardians and experts on the theoretical foundation
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19 409 of the concept of participation and the demarcation from the concept of activities, and
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21 410 compose a draft for a new participation assessment instrument in German language, which
22
23 411 will be piloted and psychometrically tested. The results can be used for further research and
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25 412 development processes and for the practice of rehabilitation planning. With the knowledge
26
27 413 about the theoretical foundation of the participation concept, the present model of the ICF-
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29 414 CY can be extended or concretized.
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4
5 417 application, and AF wrote the study protocol for the Ethics Review Committee. LH, OM, ALN
6
7 418 and JR assisted in the grant application. All authors have read and approved the final version
8
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11
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13
14 422 **Competing interests** None declared.

15
16 423 **Ethics approval** The Ethics Review Committee at the Martin-Luther-University Halle-
17
18 424 Wittenberg granted approval.

19 425 **Data statement:** The main data of this study come from interviews with young people who
20
21 426 need special protection. The ethic vote does not allow sharing of the data.

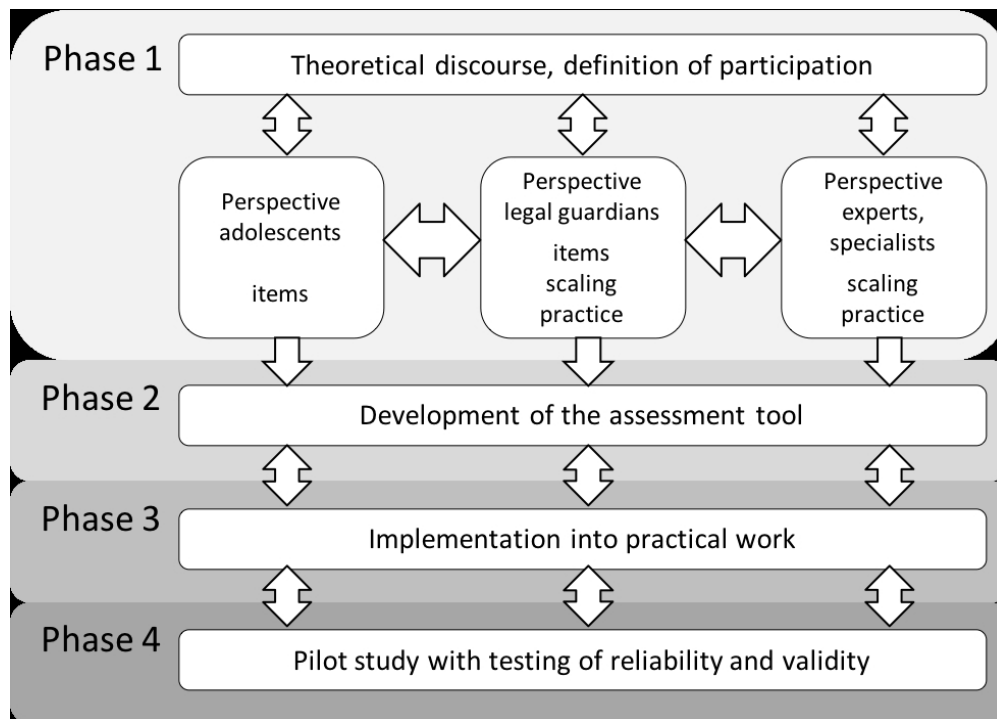
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