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Investigating the critical elements and psychosocial outcomes of Youth Flexible Assertive Community Treatment: A study protocol for an observational prospective cohort study.

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58 **ABSTRACT**

59 **Introduction**

60 When adolescents experience complex psychiatric and social problems, numerous health
61 care services usually become involved. In these cases, fragmentation of care services is a
62 risk that often results in both ineffective care and in patients disengaging from care
63 services. To address these issues, Youth Flexible ACT (Assertive Community Treatment)
64 was developed in the Netherlands. This client-centred service delivery model aims to tackle
65 the fragmented care system by providing psychiatric treatment and support in a flexible
66 and integrated manner. While Youth Flexible ACT is gaining in popularity, the effectiveness
67 of the care model remains largely unexamined.

68

69 **Methods and analysis**

70 Here, we present an observational prospective cohort in which a broad range of treatment
71 outcomes will be monitored. The primary aim of the study is to examine change in
72 treatment outcomes over the course of the Flexible ACT care. The secondary aim is to
73 examine the association between (elements of) Youth Flexible ACT model fidelity and
74 treatment outcomes. An estimated total number of 200 adolescents who receive care from
75 one of the 16 participating Youth Flexible ACT teams will be included in the study.
76 Participants will be asked to complete assessments at 4 time-points in 6-month intervals,
77 resulting in a study duration of 18 months. Latent Growth Curve Analysis of longitudinal
78 data will be used to examine (1) changes in psychosocial functioning over time and (2) the
79 relationship between changes in psychosocial functioning and model fidelity.

80

81 **Ethics and dissemination**

82 This study received ethical approval by Trimbos ethics committee (201607_75-FACT2).
83 This approval applies for all participating institutions. The results of the study will be
84 reported in accordance with the STROBE Statement. Results will be disseminated via peer-
85 reviewed academic journals and presentations at conferences. In addition, results will be
86 made available for participating sites, funders and researchers.

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Keywords

Public health, community mental health services, intensive treatment method, integrated care, flexible assertive community treatment, severe mental illness, children and adolescents, model fidelity.

For peer review only

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3 95 **ARTICLE SUMMERY**

4
5 96 **Strengths and limitations of this study**

6
7 97 - This is the first multicentre study in which the effectiveness of Youth Flexible ACT will be
8
9 98 investigated.

10
11 99 - This study will provide a complete overview of Youth Flexible ACT in which model fidelity
12
13 100 and both psychiatric and social functioning will be assessed.

14
15 101 - A strength of the study is its observational and naturalistic character which improves
16
17 102 external validity.

18
19 103 - We examine changes in treatment outcomes in a longitudinal study design, with follow-
20
21 104 up assessments up to 18 months.

22
23 105 - Primary limitation: as no variables are directly manipulated, causal inference is impeded.
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25 106

26
27 107 **INTRODUCTION**

28
29 108 About 5% of Dutch children and adolescents have a mental disorder that leads to functional
30
31 109 impairment[1, 2]. Approximately 20-30% of them have to deal with severe mental health
32
33 110 issues that require a more intensive and integrated form of care[3]. In addition to
34
35 111 psychiatric problems, these adolescents experience various difficulties in everyday life,
36
37 112 including problems with education, employment, peer relationships, family, housing,
38
39 113 finances, health, substance abuse, and issues with the criminal justice system. These
40
41 114 difficulties hinder their development and limit their ability to function well in society[4].

42
43 115 Adolescents and their relatives are often required to act as the central communicators and
44
45 116 coordinators of the care they receive. This active role requires motivation and a fairly high
46
47 117 level of knowledge about the health care system, which is often too challenging for
48
49 118 adolescents with complex care needs. In addition, health care providers themselves often
50
51 119 struggle to manage multiple health care issues of their patients due to limited
52
53 120 communication and coordination between health care providers[5, 6]. As a result,
54
55 121 treatment disengagement and dropout are common[7, 8]. Together, this calls for a model
56
57 122 of care that provides longitudinal, comprehensive, flexible and assertive care. Youth
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1
2
3 123 Flexible Assertive Community Treatment (Youth Flexible ACT) is designed to meet those
4
5 124 demands.

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7
8 125 Youth Flexible ACT is a client-centred service delivery model for community mental
9
10 126 health care that provides assertive outreach, psychiatric treatment and support with daily
11
12 127 living, adapted to the individual needs. The primary focus is to set up a collaborative effort
13
14 128 with adolescents, families and their (in)formal networks while working on shared goals
15
16 129 aimed at improving their participation in the community and enhancing their quality of
17
18 130 life[4]. Youth Flexible ACT consists of a multidisciplinary team of professionals who deliver
19
20 131 a complete range of services on a continuum of care.

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22 132

23 24 133 **Previous research into (Flexible) ACT and Youth (Flexible) ACT**

25
26 134 Flexible ACT is a Dutch adaptation and elaboration of Assertive Community Treatment
27
28 135 (ACT), which originated in the United States in the 1970s[9, 10]. ACT is a well-known
29
30 136 approach for individuals with severe mental illness that has been studied extensively,
31
32 137 spread widely throughout the world and became embedded in the Dutch Multidisciplinary
33
34 138 Schizophrenia Guideline[11-13]. Studies summarized in a Cochrane Database Systemic
35
36 139 Review provide strong evidence that ACT can increase engagement with treatment, reduce
37
38 140 hospitalization, and leads to improvements in social domains, including stable housing,
39
40 141 employment and patient satisfaction compared to the care as usual[13]. However, studies
41
42 142 conducted after the initial Cochrane Review in 1998, mostly outside the US, have shown
43
44 143 mixed results[14-15]. For example, the German ACCESS study revealed that ACT was
45
46 144 associated with symptomatic and functional improvements and better service engagement
47
48 145 in patients with schizophrenia-spectrum disorders compared to standard care[16]. A recent
49
50 146 Chinese study showed positive results in terms of hospital readmission, symptoms and
51
52 147 relapse, employment, social and occupational functioning, and quality of life of
53
54 148 caregivers[17]. However, the British REACT study found no effects on clinical and social
55
56 149 outcomes and hospitalization[18]. Additionally, a Dutch study did not find a difference
57
58 150 between ACT and standard care in reducing admission days and clinical outcomes[19].
59
60

1
2
3 151 These inconsistent findings could be due to low ACT model fidelity or insufficient contrast
4
5 152 between experimental and control conditions, since treatment as usual gradually
6
7 153 incorporates elements of assertive community treatment[14, 15, 20].
8

9 154 While ACT is indicated for the most vulnerable patients with severe mental illness
10
11 155 (predominantly psychotic disorders) who have the greatest needs for care, Flexible ACT
12
13 156 delivers care for a broader group of patients with severe mental illness[9, 10]. For stable
14
15 157 patients, Flexible ACT provides multidisciplinary treatment and support through individual
16
17 158 case management. For unstable patients, it provides intensive care offered by the same
18
19 159 team[21]. Flexible ACT allows for flexible delivery of different modes of care according to
20
21 160 the stability of the patient, in turn enhancing continuity of care[10]. The flexible ACT model
22
23 161 was developed in the Netherlands in 2003. Over the last ten years, the model has been
24
25 162 widely implemented in the Dutch mental health care system (roughly 300 teams[21]).
26
27 163 Lately, the Flexible ACT model has gained considerable interest in England, Canada, and
28
29 164 Scandinavia[21-23].
30

31 165 However, despite the enthusiasm of service providers, the evidence base for the
32
33 166 effectiveness of the adult Flexible ACT model remains sparse[24-26]. Preliminary results
34
35 167 have shown increased symptomatic remission of psychotic symptoms in patients with
36
37 168 severe mental illness compared to controls receiving standard treatment[27], higher levels
38
39 169 of psychosocial functioning[28], fewer hospital admissions and reduction of inpatient bed
40
41 170 use[23][29], and increased compliance with treatment, decrease in unmet needs, and
42
43 171 improved quality of life[30]. Flexible ACT has been shown to be more cost-effective
44
45 172 compared to assertive outreach teams in England due to reductions in bed-use, face-to-
46
47 173 face contacts, and changes in staffing[23].
48

49 174 Outcomes of Youth Flexible ACT, which was introduced in the Netherlands in 2011,
50
51 175 are reported in two reports published in the Dutch literature. Both studies were
52
53 176 uncontrolled pre-post studies, and they showed preliminary positive outcomes in that
54
55 177 patients' behavioural problems, problems with family life, hallucinations and delusions[8],
56
57 178 attention problems, emotional symptoms, self-injury and peer problems improved[31].
58
59 179 However, no improvement was found in the quality of life of the adolescents[31].
60

1
2
3 180 The broader domain of youth ACT is also limited to pre-post studies with small
4
5 181 samples, which have reported similar positive outcomes, such as improvements in
6
7 182 psychiatric condition[32][33][34], improved global functioning and increased life
8
9 183 skills[35], and decreased number of days in hospital[35-37]. Moreover, a Swiss study
10
11 184 showed that Youth ACT results in improved daily functioning and clinical benefits[38].

12
13 185 In the field of assertive outreach for adolescents, the largest controlled studies
14
15 186 involved evaluations of early psychosis programs. The Danish OPUS study demonstrated
16
17 187 that patients receiving an assertive intervention for two years had fewer psychotic
18
19 188 symptoms and decreased substance use, increased adherence to medication, and
20
21 189 increased treatment satisfaction[39]. Furthermore, a randomized controlled trial conducted
22
23 190 in England indicated that (a variant of) ACT was superior to standard care for maintaining
24
25 191 contact with professionals and reducing readmissions[40]. Finally, a Dutch quasi-
26
27 192 experimental study showed positive effects of ACT on measures of psychopathology,
28
29 193 psychosocial functioning, and quality of life[41]. Altogether, research of integrated
30
31 194 outreach models for youth and adolescents supports the effectiveness of the Youth Flexible
32
33 195 ACT model.

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35 196

37 197 **Research into (Flexible) ACT model fidelity**

38
39 198 Studies on the effectiveness of (Flexible) ACT raised the issue of identifying essential
40
41 199 elements of the model and investigated model fidelity, which reflects the degree to which
42
43 200 different elements of the model are implemented in full accordance with the model[42].
44
45 201 Studies have pointed out that higher ACT model fidelity is associated with improved
46
47 202 outcomes for patients, such as level of daily functioning and less homeless days[43-46].
48
49 203 Specifically, the typical team structure of ACT with shared caseloads and daily team
50
51 204 meetings has been found to be associated with better daily functioning[45] and decreased
52
53 205 hospitalization rates[47]. Furthermore, a positive association was found between the
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55 206 presence of consumer-providers, improvements in daily functioning, and the number of
56
57 207 homeless days[48]. Nevertheless, no studies have examined critical elements related to
58
59 208 effectiveness of Youth Flexible ACT.

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3 2094
5 210 **Purpose of the present study**

6
7 211 Although the Youth Flexible ACT model has been well received by mental health
8
9 212 professionals, its popularity has been increasing, and national Flexible ACT and
10
11 213 (inter)national ACT studies have provided promising results, little evidence exists to
12
13 214 support this particular model. Much research has focused only on adults, and the results
14
15 215 have yielded coarse outcomes based merely on small study populations. Additionally, as
16
17 216 the health care sector has been deinstitutionalized over the years, it is necessary to study
18
19 217 Youth Flexible ACT in the current health care landscape.

20
21
22 218 The present study is an observational longitudinal study in which a broad range of
23
24 219 psychosocial treatment outcomes will be monitored over time. The general objective of the
25
26 220 present study is to give insight into outcomes of Youth Flexible ACT while exploring the
27
28 221 Youth Flexible ACT population characteristics, content and process of care, and health care
29
30 222 utilization. The study addresses three research questions: 1) improvement in treatment
31
32 223 outcomes over the course of the Flexible ACT care, 2) associations between Youth Flexible
33
34 224 ACT model fidelity and treatment outcomes, and 3) associations between specific critical
35
36 225 elements of the youth Flexible ACT model and treatment outcomes. This study is of an
37
38 226 explorative nature to the extent that no similar study has been conducted on the youth
39
40 227 population. However, reasonable expectations based on the adult literature can be
41
42 228 generated, as follows: 1) psychosocial problems of adolescents will decrease when treated
43
44 229 by a Youth Flexible ACT team and 2) high model fidelity will be associated with a decrease
45
46 230 in psychosocial problems.

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49 23150
51 23252
53 233 **METHODS AND ANALYSIS**54
55 234 **Design**

56
57 235 The present study is an 18 months observational prospective cohort study in which patient
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59 236 outcomes and Youth Flexible ACT model fidelity will be assessed in 16 certified outpatient
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3 237 Youth Flexible ACT teams. The teams are located in different regions in the Netherlands.
4
5 238 An estimated number of 200 adolescents receiving care from a Youth Flexible ACT team
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7 239 will be included in the study. The data collection started in 2017 and will end in February
8
9 240 2021. The results of the study will be reported in accordance with the STROBE
10
11 241 Statement[49].
12

13 242

15 243 **Patient involvement**

17 244 This study is designed by a team of researchers and mental health workers. Before the
18
19 245 start of the data collection, we've received input from a peer support worker and from two
20
21 246 patients that matched the study's inclusion criteria. They provided input about the study
22
23 247 design, information letter, recruitment process and duration of assessments. Results will
24
25 248 be disseminated via scientific journals, presentations at conferences and will be made
26
27 249 available at participating sites.
28

29 250

31 251 **Participants**

33 252 The study population comprises 12 to 23 years old adolescents who just entered Youth
34
35 253 Flexible ACT care at one of the following mental healthcare organizations throughout the
36
37 254 Netherlands:

39 255 - Accare

41 256 - GGZ Noord Holland Noord

43 257 - GGZ Oost Brabant

45 258 - Kenter Jeugdhulp

47 259 - Lucertis

49 260 - Mondriaan-Gastenhof

51 261 - Triversum

53 262

56 263 **Inclusion criteria**

57 264 Participants eligible for Youth Flexible ACT care will be included in the study if they:

59 265 - are diagnosed with a mental health disorder (or presumptive diagnosis)
60

- 1
2
3 266 - have problems in several areas of life
4
5 267 - face family system problems and/or parenting issues
6
7 268 - do not currently receive other forms of mental health care or the care is not sufficient
8
9 269 - live in the district of the Youth Flexible ACT team
10

11 270

12
13 271 Participants will be included in the study if they meet the following additional criteria:

- 14
15 272 - participants must be 12 to 23 years of age
16
17 273 - participants must have sufficient knowledge of the Dutch language both spoken and
18
19 274 written
20
21 275 - participants and their parent/caregiver must provide a written informed consent
22

23 24 276 **Recruitment and assessments**

25
26 277 During the intake process, team members of Youth Flexible ACT teams will ask eligible
27
28 278 adolescents to participate in the study. After signing informed consent, participants will be
29
30 279 asked to complete assessments at 4 time points in 6-month intervals; hence, the study
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32 280 will last 18 months. The baseline assessment will be conducted at the start of the Youth
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34 281 Flexible ACT care with a 8-week margin. During each assessment, adolescents,
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36 282 parent/caregivers, and mental health worker will complete a set of questionnaires. These
37
38 283 questionnaires will be completed during a regular appointment by a familiar mental health
39
40 284 worker at a preferred location. The participants will be able to complete paper or online
41
42 285 questionnaires. An online data system (RoQua) will be used to collect the data. Participants
43
44 286 who will drop out of Youth Flexible ACT care or will be discharged still will be able to
45
46 287 participate in the study. With the adolescents' permission, the researchers will contact
47
48 288 them and send a link to the questionnaires by email. The subsequent measurements will
49
50 289 then be labelled as follow-up measurements.
51

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53 54 291 **Youth Flexible ACT**

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56 292 Youth Flexible ACT is a community-based mental health service that is indicated when
57
58 293 regular outpatient treatment is insufficient. These community-focused and flexible teams
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3 294 provide long-term assertive outreach care consisting of both treatment for psychiatric
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5 295 symptoms and practical assistance with daily living needs, rehabilitation, and recovery
6
7 296 support. Youth Flexible ACT care is provided by an integrated team with various
8
9 297 professional disciplines, including psychiatrists, nurses, psychologists, employment
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11 298 specialists, psychiatric nurses, addiction specialists, peer support workers, social workers,
12
13 299 and family and systemic therapists. Team members visit the patients at their home or at
14
15 300 other preferred locations and provide assertive care when necessary. Time will be devoted
16
17 301 to build and maintain trust between mental health workers and patients and to motivate
18
19 302 patients to receive treatment and support. Mental health workers have a small caseload
20
21 303 (1:15) and deliver two modes of care: individual case management and intensive team
22
23 304 care. Patients receiving individual care have a case manager and a head practitioner
24
25 305 (psychiatrist, healthcare-, or clinical psychologist). Other team members can be added, as
26
27 306 needed, for specific elements of treatment or support. A patient who is in need of extra
28
29 307 care will receive intensive care from several team members. These patients are listed on
30
31 308 a digital board, and the team discusses them every day to decide which form of care should
32
33 309 be provided and by which team members. When the crisis or the need for intensive care is
34
35 310 over, individual case management is resumed.

37 311 Youth Flexible ACT, in which the family system plays a major part, has additional
38
39 312 features beyond those that are part of Flexible ACT for adults. In particular, it is important
40
41 313 to support the following four developmental tasks[4, 8]: shaping changing relationships
42
43 314 within the family (moving from dependence to autonomy), stimulating contact with peers
44
45 315 (peers become more important as reference group as the influence of parents decreases),
46
47 316 participating in education or work, and filling leisure time. Furthermore, the possibilities
48
49 317 for personal growth and the utilization and cultivation of personal strength are emphasized
50
51 318 instead of mental health disorder symptoms.

53 319 Youth Flexible ACT is primarily a service delivery model. It describes the
54
55 320 organization of care for adolescents with complex care needs. The Flexible ACT model does
56
57 321 not dictate the specific content of a treatment plan, although the use of evidence-based
58
59 322 practices is advised. The degree to which teams implement these guidelines determines

1
2
3 323 the level of model fidelity. With high Flexible ACT model fidelity, a complete
4
5 324 multidisciplinary team provides the desirable treatment and support according to the
6
7 325 guidelines. A more detailed portrayal of (Youth) Flexible ACT is outlined in the (Youth)
8
9 326 Flexible ACT model description[4, 21, 50].
10

327

13 328 **Training**

15 329 To increase the reliability of assessments, all mental health workers involved in data
16
17 330 collection were trained in administering the questionnaires before baseline assessments.
18
19 331 In particular, mental health workers received a HoNOSCA training based on the official
20
21 332 training[51]. To examine interrater agreement of the HoNOSCA, original case vignettes
22
23 333 were used. The training consisted of a HoNOSCA information lesson, completing a training
24
25 334 vignette and discussion. Subsequently, 82 mental health workers of 13 participating teams
26
27 335 completed the actual vignette of which scores were analysed.

29 336 Intraclass correlations (ICC) were calculated as a measure of agreement between
30
31 337 raters of a single vignette based on absolute agreement using two-way mixed-effects
32
33 338 model. Statistical analyses were performed using IBM SPSS Statistics version 22.0. The
34
35 339 resulting ICC between raters ranged from moderate to good agreement: ICC average
36
37 340 measures = 0.99 (95 CI: 0.98 – 1.00) and ICC single measures = 0.57 (95 CI: 0.40 –
38
39 341 0.78). The findings indicate a moderate degree of agreement between ratings within an
40
41 342 item and between items. Since a single vignette was used, the results reflect the
42
43 343 agreement between raters and do not reveal the reliability of scale items.
44

344

47 345 **Study outcome measures**

49 346 Outcome assessments at each time point will include self-report, parent-report, and
50
51 347 clinician ratings, as displayed in Table 1.
52

348

349

Variable	Instrument	Time of assessment in
----------	------------	-----------------------

		months
Clinician ratings		
Daily functioning	HoNOSCA	T0 T6 T12 T18
Demographics	Demographics questionnaire	T0
Content of care	Content of care questionnaire	T6 T12 T18
Self-report		
Psychosocial functioning	SDQ	T0 T6 T12 T18
Quality of life	Kidscreen-10 + additional questions	T0 T6 T12 T18
Depressive symptoms	CDI-2	T0 T6 T12 T18
Social support	scale 'relationship with friends' from the Kidscreen-52	T0 T6 T12 T18
Empowerment	subscale 'interactional empowerment' from the questionnaire EMPO 2.0	T0 T6 T12 T18
Psychosis risk screening	PQ-16	T0 T6 T12 T18
Treatment satisfaction	4 brief questions based on the Jeugdthermometer	T0 T6 T12 T18
Care utilization	Care utilization questionnaire	T0
Care utilization and coordination	Care utilization and coordinator questionnaire	T6 T12 T18
Parent-report		
Psychosocial functioning - child	SDQ-P	T0 T6 T12 T18
Quality of life - child	Kidscreen-10 parent version	T0 T6 T12 T18
Mental health status	MHI-5	T0 T6 T12 T18
Parenting stress	OBVL-K	T0 T6 T12 T18
Treatment satisfaction	4 questions based on the Jeugdthermometer parent version	T0 T6 T12 T18

350

351 Table 1. Overview of outcome assessments.

352

353 1. Clinician ratings

354 *Daily functioning.* The Dutch version of the 'Health of the National Outcome Scales for
 355 Children and Adolescents' (HoNOSCA)[52] is a global scale measuring daily functioning
 356 and mental health status. All 15 items are rated on a 5-point scale indicating the severity
 357 of problems ranging from no problem (0) to severe problem (4).

358 *Demographics.* This questionnaire consists of 6 multiple-choice questions, including
 359 questions about the highest education attainment and the patient's referrer. Along with
 360 data collected from electronic patient files, this questionnaire provides socio-demographic
 361 data of the Youth Flexible ACT population.

362 *Content of care.* This questionnaire consists of 7 multiple-choice questions and provides

363 insight into the content of care offered to the patients, including the diagnoses, treatment,
364 and frequency of visits.

365

366 2. Self-report

367 *Psychosocial functioning.* The Strengths and Difficulties Questionnaire (SDQ) is a brief
368 behavioural screening questionnaire for children and adolescents[53, 54]. It includes 20
369 questions measuring emotional, conduct, and hyperactivity/inattention symptoms and
370 peer problems (excluding the dimension prosocial behaviour) over the past 6 months on a
371 3-point Likert scale ranging from 0 (not true) to 2 (certainly true).

372 *Quality of Life.* The Kidscreen-10 is a 10-item questionnaire measuring the quality of
373 life[55]. Items are rated on a 5-point Likert scale ranging from 0 (never) to 5 (always). In
374 addition to these 10 brief questions, the adolescents will be asked complete additional
375 questions concerning important areas of daily living needs, such as finance, education or
376 housing.

377 *Depressive symptoms.* Depressive symptoms will be measured using the Dutch translation
378 of the Child Depression Inventory 2 (CDI-2)[56, 57]. The CDI-2 consists of 28 items
379 measured on a 3-point scale ranging from 0 (depressive symptom is absent) to 2
380 (depressive symptom is always present).

381 *Social support.* To measure social support, the scale 'relationship with friends' from the
382 Kidscreen-52[58] will be used. This scale examines the quality of the interaction between
383 adolescents using six items, for example, 'did you have fun with friends?'. The items are
384 measured on a 5-point Likert scale ranging from 0 (never) to 4 (always). Two additional
385 questions about satisfaction with social support will be imbedded.

386 *Empowerment.* Empowerment will be measured with the subscale 'interactional
387 empowerment' from the questionnaire EMPO 2.0[59], which assesses the willingness to
388 change undesired situations, looking for solutions, and knowing how to access resources.
389 The subscale comprises 6 questions measured on a 5-point Likert scale ranging from 1
390 (strongly disagree) to 5 (strongly agree).

391 *Psychosis risk screening.* The Prodromal Questionnaire (PQ-16)[60] is a self-report

1
2
3 392 questionnaire used to screen adolescents at risk of developing psychosis. It consists of 16
4
5 393 items assessing perceptual abnormalities, unusual thought content, and negative
6
7 394 symptoms. The items are measured on a 4-point Likert scale ranging from 0 (no distress)
8
9 395 to 4 (severe distress).

10
11 396 *Treatment satisfaction.* Satisfaction with treatment will be measured with 4 brief questions
12
13 397 based on the Jeugdthermometer[61]. Treatment satisfaction is rated on a scale from 1
14
15 398 (very bad) to 10 (very good).

16
17 399 *Care utilization.* Care utilization will be measured with one multiple choice question about
18
19 400 the received care prior to the Youth Flexible ACT care.

20
21 401 *Care utilization and coordination.* Care utilization will be measured with one question about
22
23 402 the received care in addition to the received Youth Flexible ACT care. Care coordination will
24
25 403 be measured using one question assessing the satisfaction between the cooperation with
26
27 404 the Youth Flexible ACT team and other health care facilities on a scale from 1
28
29 405 (unsatisfactory) to 10 (very satisfactory).

30
31 406

32 33 407 3. Parent-report

34
35 408 *Psychosocial functioning.* The SDQ-P (Strengths and Difficulties Questionnaire) is the
36
37 409 parent version of the SDQ, as described above[53].

38
39 410 *Quality of Life.* The Kidscreen-10 parent report is the parent-version of the Kidscreen-10,
40
41 411 a 10-item questionnaire on quality of life, as described above[55].

42
43 412 *Mental health status.* The Mental Health Inventory (MHI-5) is a brief questionnaire
44
45 413 assessing general mental health[62] and is part of the Short Form Health Survey (SF-36),
46
47 414 a questionnaire measuring health-related quality of life. The MHI-5 consists of 5 items
48
49 415 scored on a 6-point Likert scale ranging from 1 (all of the time) to 6 (none of the time).

50
51 416 *Parenting Stress.* Parenting stress will be measured using the short version of the
52
53 417 Opvoeding Belasting Vragenlijst (OBVL-K)[63]. The questionnaire focuses on the quality of
54
55 418 the parent-child relationship measured using 10 items rated on a 4-point scale ranging
56
57 419 from 1 (not true) to 4 (very true).

1
2
3 420 *Treatment satisfaction.* Satisfaction with treatment will be measured using 4 brief
4
5 421 questions based on the Jeugdthermometer parent version[61]. The items are rated on a
6
7 422 scale from 1 (very bad) to 10 (very good).
8

9 423

10 11 424 4. Youth Flexible ACT model fidelity

12
13 425 The association between psychosocial functioning of adolescents and (elements of) model
14
15 426 fidelity will be studied. The level of implementation of the model will be measured with the
16
17 427 Youth Flexible ACT scale (Youth FACTs) developed by the Centre for Certification ACT and
18
19 428 Flexible ACT (CCAF) in 2014[42]. The CCAF was established in the Netherlands in 2008 by
20
21 429 Dutch mental health care professionals and researchers to ensure the quality of ACT and
22
23 430 Flexible ACT. By executing audits to measure the level of implementation, teams can obtain
24
25 431 a Youth Flexible ACT implementation certificate. The Youth FACTs consists of 62 items
26
27 432 measuring 7 main elements: team structure (15 items), team process (12 items),
28
29 433 diagnostics, treatment and interventions (12 items), organization of services (11 items),
30
31 434 community care (5 items), monitoring (3 items), and level of professionalization (4 items).
32
33 435 Two independent raters from CCAF will score the Youth FACTs on a five-point rating scale
34
35 436 ranging from 1 (minimum implementation) to 5 (maximum implementation). The CCAF
36
37 437 defines a total score on the Youth FACTs of 3.0 and lower as insufficient implementation
38
39 438 while scores between 3.1 and 3.3 indicate a temporary certificate for 1 year, with
40
41 439 improvements to be made to obtain a final certificate. Scores 3.4 to 4.0 are sufficient to
42
43 440 receive the certificate while scores of 4.1 and higher are regarded as excellent. If a team
44
45 441 has received a certificate, it remains valid for three years. During this period, the team is
46
47 442 expected to report any major changes, including reorganizations and divisions, to the
48
49 443 CCAF. Because some Youth Flexible ACT teams are already certified before the start of this
50
51 444 study, an audit will take place according to their current certification process.
52

53 445

54 446 5. Administrative data

55
56 447 Electronic patient records will be consulted for the following outcomes:

57
58 448 *Diagnoses.* DSM-IV-TR (Diagnostic and Statistical Manual of Mental Disorders)

1
2
3 449 classifications and Global Assessment of Functioning (GAF) scores will be collected[64].

4
5 450 *Admission days.* Admission rate and admission duration will be collected.

6
7 451 *Treatment duration.* Flexible ACT care start date and treatment duration.

8
9 452

10 11 453 **Statistical analysis**

12
13 454 The main hypothesis of this study states that higher Youth Flexible ACT model fidelity will
14
15 455 lead to greater improvements in psychosocial functioning over time. Latent Growth Curve
16
17 456 Analysis will be used to examine change in psychosocial functioning over time (T0, T6,
18
19 457 T12, T18 in months) and its relation to model fidelity. This change over time will be
20
21 458 calculated with growth parameters (intercept, linear slope and possible quadratic factor)
22
23 459 for each patient. For each of the study outcomes, the best fit function (model) will be
24
25 460 assessed to measure change in outcomes. Control variables (age, gender and diagnoses
26
27 461 of patients) will be included as covariates in the growth model. In addition, the multiple
28
29 462 elements of model fidelity will be used as predictors of the growth parameters. Regression
30
31 463 coefficients will indicate the extent to which these elements contribute to these parameters.
32
33 464 To deal with missing values, the Full Information Maximum Likelihood estimator, or the
34
35 465 using-all-available information method, will be used.

36
37 466 Furthermore, the data will be clustered within subjects and teams. Seven mental
38
39 467 health institutions will participate in the study, with a total of 16 teams and an expected
40
41 468 average of 20 patients per team. If the results of this study demonstrate substantial
42
43 469 variation between the participating teams, analysis will be performed to account for team
44
45 470 effects.

46
47 471

48 49 472 **Sample size calculation**

50
51 473 Given the practical challenges in conducting a multicentre study with a complex
52
53 474 intervention, the aim of this study is to achieve maximum participation[65]. A power
54
55 475 analysis for a paired t-test with G*power indicated that a minimum of 156 patients will
56
57 476 have to be recruited to achieve a power of 0.80, an alpha of 0.05, and an effect size of
58
59 477 0.20 (one-tailed). Slightly more patients will be required (n = 165) for a small slope effect

1
2
3 478 of a linear latent growth model[66]. When accounting for missing values, a target sample
4
5 479 size of 200 participants should be sufficient.
6

7 480

8 9 481 **DISCUSSION**

10 11 482 **Preliminary reflection on the limitations and strengths of the design**

12
13 483 The observational and naturalistic character of the study design is both its weakness and
14
15 484 its strength. Conclusions are restricted to associations between Youth Flexible ACT care
16
17 485 and treatment outcome with the obtained data. No causal relationships can be implied
18
19 486 because a control group is absent. Realizing a resembling control group and providing them
20
21 487 treatment as usual is practically impossible to achieve, due to the complexity of the
22
23 488 psychosocial problems, vulnerability to mental health crisis and an extensive avoidance of
24
25 489 mental health services. Additionally, as it is difficult to find a resembling study population,
26
27 490 it is not possible to match the research results with a data set of another comparable cohort
28
29 491 study. Furthermore, as a consequence of a naturalistic study design, the data obtained in
30
31 492 the practical field of mental healthcare is subject to transitions and developments during
32
33 493 data collection (e.g., changes in team structure).

34
35 494 Nevertheless, an important strength of the current study is its strong external
36
37 495 validity, as youth Flexible ACT will be studied as it is used in daily practice[67]. Another
38
39 496 strength of the study is its longitudinal design with follow-up assessments up to 18 months,
40
41 497 providing the opportunity to evaluate long-term effects. Furthermore, examining a broad
42
43 498 set of outcomes (both psychiatric and social functioning) allows for a more complete view
44
45 499 of Youth Flexible ACT, since the data on participant and service characteristics will be
46
47 500 collected from a large sample of patients and mental health workers.
48

49 501

50 51 502 **Implications for clinical practice**

52
53 503 When adolescents experience complex problems affecting various aspects of their lives,
54
55 504 fragmentation of care services can lead to inconsistent and ineffective care. Youth Flexible
56
57 505 ACT actively engages adolescents in treatment and provides a flexible response to the
58
59 506 needs in different stages of care that enhances continuity of care. By providing assertive

1
2
3 507 and integrated treatment, Youth Flexible ACT aims to tackle this fragmented mental health
4
5 508 care system. The present study will contribute to clinical practice by providing insights into
6
7 509 the effectiveness of Youth Flexible ACT and the essential elements responsible for the
8
9 510 effect. This will provide valuable information for mental health care organizations, funding
10
11 511 organizations, and policymakers on how to maximize the quality of care for a vulnerable
12
13 512 group of adolescents for whom the existing regular outpatient mental healthcare is hardly
14
15 513 suitable.

16
17 514

18 19 515 **ETHICS AND DISSEMINATION**

20
21 516 The medical ethics committee CMO Region Arnhem-Nijmegen in the Netherlands concluded
22
23 517 that the present study (NL57443.091.16) does not require medical ethical approval. In
24
25 518 addition, this study received ethical approval by Trimbos ethics committee (201607_75-
26
27 519 FACT2). The Trimbos Institute is the Netherlands Institute of Mental Health and Addiction,
28
29 520 a non-profit research and knowledge center that reviews non-WMO research projects. This
30
31 521 committee ruled that our protocol complies with all applicable regulations. This approval
32
33 522 applies for all participating institutions. Written informed consent from adolescents and
34
35 523 parents or legal guardians will be obtained. The results of the study will be reported in
36
37 524 accordance with the STROBE Statement. Results will be disseminated via peer-reviewed
38
39 525 academic journals and presentations at conferences. In addition, results will be made
40
41 526 available for participating sites, funders and researchers.

42
43 527

44 45 528 **AUTHOR CONTRIBUTIONS**

46
47 529 MB will be responsible for data collection and data analysis as well as for reporting the
48
49 530 study results. AV will support the data analysis. DC, NF, and HK read the manuscript and
50
51 531 provided suggestions for improvement. DC, NF, and HK also serve as supervisors. All
52
53 532 authors read and approved the final manuscript.

54
55 533

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58
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1
2
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4
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6
7 538 approving the present protocol. The Olim Foundation has no role in the collection, analysis
8
9 539 and interpretation of data, or in the writing of manuscripts. Additionally, each of the six
10
11 540 participating institutions will pay a small contribution of €7600,- to cover research material
12
13 541 expenses including online data managing systems. Finally, the Trimbos Institute will
14
15 542 provide the necessary research expertise.
16

17 543

18
19 544 **COMPETING INTERESTS**

20
21 545 None declared.
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STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract Title, page number 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found Abstract, page numbers 3-4
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported Background, page numbers 6-9
Objectives	3	State specific objectives, including any prespecified hypotheses Background, page numbers 9-10
Methods		
Study design	4	Present key elements of study design early in the paper Methods, page number 10
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection Methods, page numbers 10-11
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Methods, page numbers 10-12
		(b) For matched studies, give matching criteria and number of exposed and unexposed N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable Methods, page numbers 14-18
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group Methods, page numbers 11-18
Bias	9	Describe any efforts to address potential sources of bias Discussion, page numbers 19-20
Study size	10	Explain how the study size was arrived at Methods, page number 19
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why N/A (study protocol)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding Methods, page number 18
		(b) Describe any methods used to examine subgroups and interactions Methods, page number 18
		(c) Explain how missing data were addressed Methods, page number 18
		(d) If applicable, explain how loss to follow-up was addressed Methods, page number 18
		(e) Describe any sensitivity analyses N/A (study protocol)

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed Methods, page number 19
		(b) Give reasons for non-participation at each stage N/A (study protocol)
		(c) Consider use of a flow diagram N/A (study protocol)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders N/A (study protocol)
		(b) Indicate number of participants with missing data for each variable of interest N/A (study protocol)
		(c) Summarise follow-up time (eg, average and total amount) N/A (study protocol)
Outcome data	15*	Report numbers of outcome events or summary measures over time N/A (study protocol)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included N/A (study protocol)
		(b) Report category boundaries when continuous variables were categorized N/A (study protocol)
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period N/A (study protocol)
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses Methods, page number 13
Discussion		
Key results	18	Summarise key results with reference to study objectives N/A (study protocol)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Discussion, page numbers 19-20
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence N/A (study protocol)
Generalisability	21	Discuss the generalisability (external validity) of the study results Discussion, page numbers 19-20
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based Funding, page number 22

*Give information separately for exposed and unexposed groups.

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Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.

For peer review only

BMJ Open

Investigating the critical elements and psychosocial outcomes of Youth Flexible Assertive Community Treatment: A study protocol for an observational prospective cohort study.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-035146.R1
Article Type:	Protocol
Date Submitted by the Author:	26-Feb-2020
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Primary Subject Heading:	Public health
Secondary Subject Heading:	Mental health
Keywords:	Child & adolescent psychiatry < PSYCHIATRY, Community child health < PAEDIATRICS, PUBLIC HEALTH

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3 1 **TITLE PAGE**
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9 4 Investigating the critical elements and psychosocial outcomes of Youth Flexible Assertive
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11 5 Community Treatment: A study protocol for an observational prospective cohort study.
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15 7 **Word count**
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58 **ABSTRACT**

59 **Introduction**

60 When adolescents experience complex psychiatric and social problems, numerous health
61 care services usually become involved. In these cases, fragmentation of care services is a
62 risk that often results in both ineffective care and in patients disengaging from care
63 services. To address these issues, Youth Flexible ACT (Assertive Community Treatment)
64 was developed in the Netherlands. This client-centred service delivery model aims to tackle
65 the fragmented care system by providing psychiatric treatment and support in a flexible
66 and integrated manner. While Youth Flexible ACT is gaining in popularity, the effectiveness
67 of the care model remains largely unexamined.

69 **Methods and analysis**

70 Here, we present an observational prospective cohort (2017-2021) in which a broad range
71 of treatment outcomes will be monitored. The primary aim of the study is to examine
72 change in treatment outcomes over the course of the Flexible ACT care. The secondary
73 aim is to examine the association between (elements of) Youth Flexible ACT model fidelity
74 and treatment outcomes. An estimated total number of 200 adolescents who receive care
75 from one of the 16 participating Youth Flexible ACT teams will be included in the study.
76 Participants will be asked to complete assessments at 4 time-points in 6-month intervals,
77 resulting in a study duration of 18 months. Latent Growth Curve Analysis will be conducted
78 to examine change in psychosocial functioning over time and its relation to model fidelity.

80 **Ethics and dissemination**

81 This study received ethical approval by Trimbos ethics committee (201607_75-FACT2).
82 This approval applies for all participating institutions. The results of the study will be
83 reported in accordance with the STROBE Statement. Results will be disseminated via peer-
84 reviewed academic journals and presentations at conferences. In addition, results will be
85 made available for participating sites, funders and researchers.

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87 **Keywords**

88 Public health, community mental health services, intensive treatment method, integrated
89 care, flexible assertive community treatment, severe mental illness, children and
90 adolescents, model fidelity.

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94 **ARTICLE SUMMERY**

95 **Strengths and limitations of this study**

96 - This is the first multicentre study in which the effectiveness of Youth Flexible ACT will be
97 investigated.

98 - This study will provide a complete overview of Youth Flexible ACT in which model fidelity
99 and both psychiatric and social functioning will be assessed.

100 - A strength of the study is its observational and naturalistic character which improves
101 external validity.

102 - We examine changes in treatment outcomes in a longitudinal study design, with follow-
103 up assessments up to 18 months.

104 - Primary limitation: as no variables are directly manipulated, causal inference is impeded.

105

106 **INTRODUCTION**

107 About 5% of Dutch children and adolescents have a mental disorder that leads to functional
108 impairment[1, 2]. Approximately 20-30% of them have to deal with severe mental health
109 issues that require a more intensive and integrated form of care[3]. In addition to
110 psychiatric problems, these adolescents experience various difficulties in everyday life,
111 including problems with education, employment, peer relationships, family, housing,
112 finances, health, substance abuse, and issues with the criminal justice system. These
113 difficulties hinder their development and limit their ability to function well in society[4].

114 Adolescents and their relatives are often required to act as the central communicators and
115 coordinators of the care they receive. This active role requires motivation and a fairly high
116 level of knowledge about the health care system, which is often too challenging for
117 adolescents with complex care needs. In addition, health care providers themselves often
118 struggle to manage multiple health care issues of their patients due to limited
119 communication and coordination between health care providers[5, 6]. As a result,
120 treatment disengagement and dropout are common[7, 8]. Together, this calls for a model
121 of care that provides longitudinal, comprehensive, flexible and assertive care. Youth
122 Flexible Assertive Community Treatment (Youth Flexible ACT) is designed to meet those

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3 123 demands.

4
5 124 Youth Flexible ACT is a client-centred service delivery model for community mental
6
7 125 health care that provides assertive outreach, psychiatric treatment and support with daily
8
9 126 living, adapted to the individual needs. The primary focus is to set up a collaborative effort
10
11 127 with adolescents, families and their (in)formal networks while working on shared goals
12
13 128 aimed at improving their participation in the community and enhancing their quality of
14
15 129 life[4]. Youth Flexible ACT consists of a multidisciplinary team of professionals who deliver
16
17 130 a complete range of services on a continuum of care.

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21 132 **Previous research into (Flexible) ACT and Youth (Flexible) ACT**

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23
24 133 Flexible ACT is a Dutch adaptation and elaboration of Assertive Community Treatment
25
26 134 (ACT), which originated in the United States in the 1970s[9, 10]. ACT is a well-known
27
28 135 approach for individuals with severe mental illness that has been studied extensively,
29
30 136 spread widely throughout the world and became embedded in the Dutch Multidisciplinary
31
32 137 Schizophrenia Guideline[11-13]. Studies summarized in a Cochrane Database Systemic
33
34 138 Review provide strong evidence that ACT can increase engagement with treatment, reduce
35
36 139 hospitalization, and leads to improvements in social domains, including stable housing,
37
38 140 employment and patient satisfaction compared to the care as usual[13]. However, studies
39
40 141 conducted after the initial Cochrane Review in 1998, mostly outside the US, have shown
41
42 142 mixed results[14-15]. For example, the German ACCESS study revealed that ACT was
43
44 143 associated with symptomatic and functional improvements and better service engagement
45
46 144 in patients with schizophrenia-spectrum disorders compared to standard care[16]. A recent
47
48 145 Chinese study showed positive results in terms of hospital readmission, symptoms and
49
50 146 relapse, employment, social and occupational functioning, and quality of life of
51
52 147 caregivers[17]. However, the British REACT study found no effects on clinical and social
53
54 148 outcomes and hospitalization[18]. Additionally, a Dutch study did not find a difference
55
56 149 between ACT and standard care in reducing admission days and clinical outcomes[19].
57
58 150 These inconsistent findings could be due to low ACT model fidelity or insufficient contrast
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3 151 between experimental and control conditions, since treatment as usual gradually
4
5 152 incorporates elements of assertive community treatment[14, 15, 20].
6

7 153 While ACT is indicated for the most vulnerable patients with severe mental illness
8
9 154 (predominantly psychotic disorders) who have the greatest needs for care, Flexible ACT
10
11 155 delivers care for a broader group of patients with severe mental illness[9, 10]. For stable
12
13 156 patients, Flexible ACT provides multidisciplinary treatment and support through individual
14
15 157 case management. For unstable patients, it provides intensive care offered by the same
16
17 158 team[21]. Flexible ACT allows for flexible delivery of different modes of care according to
18
19 159 the stability of the patient, in turn enhancing continuity of care[10]. The flexible ACT model
20
21 160 was developed in the Netherlands in 2003. Over the last ten years, the model has been
22
23 161 widely implemented in the Dutch mental health care system (roughly 300 teams[21]).
24
25 162 Lately, the Flexible ACT model has gained considerable interest in England, Canada, and
26
27 163 Scandinavia[21-23].
28

29 164 However, despite the enthusiasm of service providers, the evidence base for the
30
31 165 effectiveness of the adult Flexible ACT model remains sparse[24-26]. Preliminary results
32
33 166 have shown increased symptomatic remission of psychotic symptoms in patients with
34
35 167 severe mental illness compared to controls receiving standard treatment[27], higher levels
36
37 168 of psychosocial functioning[28], fewer hospital admissions and reduction of inpatient bed
38
39 169 use[23, 29], and increased compliance with treatment, decrease in unmet needs, and
40
41 170 improved quality of life[30]. Flexible ACT has been shown to be more cost-effective
42
43 171 compared to assertive outreach teams in England due to reductions in bed-use, face-to-
44
45 172 face contacts, and changes in staffing[23].
46

47 173 Outcomes of Youth Flexible ACT, which was introduced in the Netherlands in 2011,
48
49 174 are reported in two reports published in the Dutch literature. Both studies were
50
51 175 uncontrolled pre-post studies, and they showed preliminary positive outcomes in that
52
53 176 patients' behavioural problems, problems with family life, hallucinations and delusions[8],
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55 177 attention problems, emotional symptoms, self-injury and peer problems improved[31].
56
57 178 However, no improvement was found in the quality of life of the adolescents[31].
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3 179 The broader domain of Youth ACT is also limited to pre-post studies with small
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5 180 samples, which have reported similar positive outcomes, such as improvements in
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7 181 psychiatric condition[32-34], improved global functioning and increased life skills[35], and
8
9 182 decreased number of days in hospital[35-37]. Moreover, a recent Swiss study showed that
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11 183 Youth ACT results in improved daily functioning and clinical benefits[38].

12
13 184 In the field of assertive outreach for adolescents, the largest controlled studies
14
15 185 involved evaluations of early psychosis programs. The Danish OPUS study demonstrated
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17 186 that patients receiving an assertive intervention for two years had fewer psychotic
18
19 187 symptoms and decreased substance use, increased adherence to medication, and
20
21 188 increased treatment satisfaction[39]. Furthermore, a randomized controlled trial conducted
22
23 189 in England indicated that (a variant of) ACT was superior to standard care for maintaining
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25 190 contact with professionals and reducing readmissions[40]. Finally, a Dutch quasi-
26
27 191 experimental study showed positive effects of ACT on measures of psychopathology,
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29 192 psychosocial functioning, and quality of life[41]. Altogether, research of integrated
30
31 193 outreach models for youth and adolescents supports the effectiveness of the Youth Flexible
32
33 194 ACT model.

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36 37 196 **Research into (Flexible) ACT model fidelity**

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39 197 Studies on the effectiveness of (Flexible) ACT raised the issue of identifying essential
40
41 198 elements of the model and investigated model fidelity, which reflects the degree to which
42
43 199 different elements of the model are implemented in full accordance with the model[42].
44
45 200 Studies have pointed out that higher ACT model fidelity is associated with improved
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47 201 outcomes for patients, such as level of daily functioning and less homeless days[43-46].
48
49 202 Specifically, the typical team structure of ACT with shared caseloads and daily team
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51 203 meetings has been found to be associated with better daily functioning[45] and decreased
52
53 204 hospitalization rates[47]. Furthermore, a positive association was found between the
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55 205 presence of consumer-providers, improvements in daily functioning, and the number of
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57 206 homeless days[48]. Nevertheless, no studies have examined critical elements related to
58
59 207 effectiveness of Youth Flexible ACT.

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5 209 **Purpose of the present study**

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7 210 Although the Youth Flexible ACT model has been well received by mental health
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9 211 professionals, its popularity has been increasing, and national Flexible ACT and
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11 212 (inter)national ACT studies have provided promising results, little evidence exists to
12
13 213 support this particular model. Much research has focused only on adults, and the results
14
15 214 have yielded coarse outcomes based merely on small study populations. Additionally, as
16
17 215 the health care sector has been deinstitutionalized over the years, it is necessary to study
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19 216 Youth Flexible ACT in the current health care landscape.

20
21 217 The present study is an observational longitudinal study in which a broad range of
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23 218 psychosocial treatment outcomes will be monitored over time. The general objective of the
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25 219 present study is to give insight into outcomes of Youth Flexible ACT while exploring the
26
27 220 Youth Flexible ACT population characteristics, content and process of care. The study
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29 221 addresses three research questions: 1) improvement in treatment outcomes over the
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31 222 course of the Flexible ACT care, 2) associations between Youth Flexible ACT model fidelity
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33 223 and treatment outcomes, and 3) associations between specific critical elements of the
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35 224 Youth Flexible ACT model and treatment outcomes. This study is of an explorative nature
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37 225 to the extent that no similar study has been conducted on the youth population. However,
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39 226 reasonable expectations based on the adult literature can be generated, as follows: 1)
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41 227 psychosocial problems of adolescents will decrease when treated by a Youth Flexible ACT
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43 228 team and 2) high model fidelity will be associated with a decrease in psychosocial problems.

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45 22946
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49 231 **METHODS AND ANALYSIS**50
51 232 **Design**

52
53 233 The Youth Flexible ACT Study is an 18 months observational prospective cohort study that
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55 234 examines change in treatment outcomes over the course of Youth Flexible ACT care and
56
57 235 examines the association between (elements of) Youth Flexible ACT model fidelity and
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59 236 treatment outcomes. A total of 16 (non-specific) Youth Flexible ACT teams across 7 mental

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3 237 health care institutes in the Netherlands participate in the study. An estimated number of
4
5 238 200 adolescents receiving care from a Youth Flexible ACT team will be included in the
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7 239 study. Participants and their mental health workers will be asked to complete assessments
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9 240 at 4 time points in 6-month intervals. Also parents/carers were asked to participate. The
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11 241 data collection started in 2017 and is scheduled to conclude in February 2021. The results
12
13 242 of the study will be reported in accordance with the STROBE Statement[49].
14

15 243

17 244 **Patient involvement**

19 245 This study is designed in collaboration with mental health workers. Before the start of the
20
21 246 data collection, we've received input from all participating Youth Flexible ACT teams, a peer
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23 247 support worker and two Youth Flexible ACT patients. They've provided input about the
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25 248 recruitment process, information letter and (duration of) assessment battery. Results of
26
27 249 the Youth Flexible ACT Study will be disseminated via scientific journals, presentations at
28
29 250 conferences and will be made available at participating sites.
30

31 251

33 252 **Study sample**

35 253 The study sample comprises 12 to 24 years old adolescents who receive Youth Flexible
36
37 254 ACT care at one of the participating mental healthcare organizations throughout the
38
39 255 Netherlands: Accare, GGZ Noord Holland Noord, GGZ Oost Brabant, Kenter Jeugdhulp,
40
41 256 Lucertis, Mondriaan-Gastenhof, Triversum.
42

43 257

45 258 Participants receiving Youth Flexible ACT care will be included in the study if they meet the
46
47 259 following research inclusion criteria:

49 260 - participants must be 12 to 24 years of age

51 261 - participants must have sufficient knowledge of the Dutch language both spoken and
52
53 262 written

55 263 - participants and their parent/caregiver must provide a written informed consent
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264 **Study population**

265 Youth Flexible ACT provides treatment to young people with complex and severe mental
266 health problems, who have difficulty engaging in regular mental health care. Practical
267 experiences and literature indicate that these young people have a hard time accessing
268 and remaining in regular outpatient mental health care[4, 33, 38]. Several reasons for
269 treatment disengagement in adolescents have been suggested, such as fragmented health
270 care system[50], treatment discontinuity[51, 52] and difficulty to trust services[53].

271
272 According the Youth Flexible ACT model description[4] young people are eligible for Youth
273 Flexible ACT care if they:

- 274 - are diagnosed with a mental health disorder (or presumptive diagnosis)
- 275 - experience difficulties in multiple areas of daily life (for example problems with education,
276 employment, peer relationships, housing, finances, health, substance abuse, and issues
277 with the criminal justice system)
- 278 - face family system problems and/or parenting issues
- 279 - have difficulty accessing and remaining in regular outpatient care or if the regular care
280 proves to be unfruitful
- 281 - live in the district of the Youth Flexible ACT team

282 The pathway to Youth Flexible ACT care is straightforward and direct. Anyone (e.g.
283 patients' parent, care workers) in the Netherlands can directly contact a Youth Flexible ACT
284 team to suggest a potential referral when he/she thinks a patient is eligible. An intake
285 coordinator of the Youth Flexible ACT team then determines if the inclusion criteria outlined
286 above are met. If so, a referral from the general practitioner is requested before care can
287 start.

288

289 **Youth Flexible ACT**

290 Youth Flexible ACT is a community-based mental health service in which integrated teams
291 provide long-term assertive outreach care consisting of both treatment for psychiatric

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3 292 symptoms and practical assistance with daily living needs, rehabilitation, and recovery
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5 293 support. Youth Flexible ACT teams consist of various professional disciplines, including
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7 294 psychiatrists, nurses, psychologists, employment specialists, psychiatric nurses, addiction
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9 295 specialists, peer support workers, social workers, and family and systemic therapists. Youth
10
11 296 Flexible ACT encompasses a multi-agency approach that coordinates collaboration with
12
13 297 professionals from other services. Team members visit the patients at their home or at
14
15 298 other preferred locations and provide assertive care when necessary. Time will be devoted
16
17 299 to build and maintain trust between mental health workers and patients and to motivate
18
19 300 patients to receive treatment and support. Mental health workers have a small caseload
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21 301 (1:15) and deliver two modes of care: individual case management and intensive team
22
23 302 care. Patients receiving individual care have a case manager and a head practitioner
24
25 303 (psychiatrist, healthcare-, or clinical psychologist). Other team members can be added, as
26
27 304 needed, for specific elements of treatment or support. A patient who is in need of extra
28
29 305 care will receive intensive care from several team members. These patients are listed on
30
31 306 a digital board, and the team discusses them every day to decide which form of care should
32
33 307 be provided and by which team members. When the crisis or the need for intensive care is
34
35 308 over, individual case management is resumed.

37 309 Youth Flexible ACT, in which the family system plays a major part, has additional
38
39 310 features beyond those that are part of Flexible ACT for adults. In particular, it is important
40
41 311 to support the following four developmental tasks[4, 8]: shaping changing relationships
42
43 312 within the family (moving from dependence to autonomy), stimulating contact with peers
44
45 313 (peers become more important as reference group as the influence of parents decreases),
46
47 314 participating in education or work, and filling leisure time. Furthermore, the possibilities
48
49 315 for personal growth and the utilization and cultivation of personal strength are emphasized
50
51 316 instead of mental health disorder symptoms.

53 317 Youth Flexible ACT is primarily a service delivery model. It describes the
54
55 318 organization of care for adolescents with complex care needs. The Flexible ACT model does
56
57 319 not dictate the specific content of a treatment plan, although the use of evidence-based
58
59 320 practices is advised. The degree to which teams implement these guidelines determines

1
2
3 321 the level of model fidelity. With high Flexible ACT model fidelity, a complete
4
5 322 multidisciplinary team provides the desirable treatment and support according to the
6
7 323 guidelines. A more detailed portrayal of (Youth) Flexible ACT is outlined in the (Youth)
8
9 324 Flexible ACT model description[4, 21, 54].
10

11 325

12 13 326 **Recruitment and assessments**

14
15 327 During the intake process, team members of Youth Flexible ACT teams will ask eligible
16
17 328 adolescents to participate in the study. After signing informed consent, participants will be
18
19 329 asked to complete a baseline measurement within a 12-week margin. Participants will then
20
21 330 be monitored every 6 months with questionnaires, up to 4 measurements. These
22
23 331 questionnaires will be completed during a regular appointment by a familiar mental health
24
25 332 worker or participants have the option to complete the questionnaires independently in
26
27 333 their own time. It will take approximately 20-30 minutes for adolescents to complete the
28
29 334 assessment battery. Adolescent participants receive a remuneration of €10,-. Both paper
30
31 335 and online versions are available. Online versions are preferred to minimize missing data.
32
33 336 Researchers are in close contact with mental health workers and ensure that participants
34
35 337 complete the questionnaires timely. An online Dutch data system will be used to collect
36
37 338 the data. Confidentiality of the data is guaranteed through a login procedure and each
38
39 339 institution has its own digital environment. Participants that finish their treatment within
40
41 340 1.5 years will, with the adolescents' permission, receive a link to the remaining
42
43 341 questionnaires by email.
44

45 46 47 342 **Training**

48
49 343 To increase the reliability of assessments, all mental health workers involved in data
50
51 344 collection were trained in administering the questionnaires before baseline assessments.
52
53 345 In particular, mental health workers received a HoNOSCA training based on the official
54
55 346 training[55]. The HoNOSCA (Health of the National Outcome Scales for Children and
56
57 347 Adolescents)[56] is a global scale measuring daily functioning and mental health
58
59 348 symptoms. To examine interrater agreement of the HoNOSCA, original case vignettes were
60

349 used. The training consisted of a HoNOSCA information lesson, completing a training
 350 vignette and discussion. Subsequently, 82 mental health workers of 13 participating teams
 351 completed the actual vignette of which scores were analysed.

352 Intraclass correlations (ICC) were calculated as a measure of agreement between
 353 raters of a single vignette based on absolute agreement using two-way mixed-effects
 354 model. Statistical analyses were performed using IBM SPSS Statistics version 22.0. The
 355 resulting ICC between raters ranged from moderate to good agreement: ICC average
 356 measures = 0.99 (95 CI: 0.98 – 1.00) and ICC single measures = 0.57 (95 CI: 0.40 –
 357 0.78). The findings indicate a moderate degree of agreement between ratings within an
 358 item and between items. Since a single vignette was used, the results reflect the
 359 agreement between raters and do not reveal the reliability of scale items.

360 **Study outcome measures**

361 Table 1 displays an overview of outcome measures at each time point for self-report,
 362 parent-report, and clinician ratings. The employed set of questionnaires together reflect
 363 the multiple life domains in which Youth Flexible ACT operates. The combination of
 364 questionnaires assesses general psychological functioning, specific diagnostic
 365 characteristics and daily functioning of the participants.

Variable	Instrument	Time of assessment in months
Clinician ratings		
Daily functioning	HoNOSCA	T0 T6 T12 T18
Socio-demographics	Questions concerning socio-demographics	T0
Content of care	7 questions concerning content of care	T6 T12 T18
Self-report		
Psychosocial functioning	SDQ	T0 T6 T12 T18
Health related Quality of life	Kidscreen-10 + additional questions	T0 T6 T12 T18
Depressive symptoms	CDI-2	T0 T6 T12 T18
Social support	Scale 'social support and peers' from the Kidscreen-52	T0 T6 T12 T18

Empowerment	Subscale 'interactional empowerment' from the questionnaire EMPO 3.1	T0 T6 T12 T18
Psychosis risk screening	PQ-16	T0 T6 T12 T18
Treatment satisfaction	4 brief questions based on the Jeugdthermometer	T0 T6 T12 T18
Care utilization	1 question concerning care utilization	T0
Care utilization and coordination	2 questions concerning care utilization and coordination	T6 T12 T18
Parent-report		
Psychosocial wellbeing - child	SDQ-P	T0 T6 T12 T18
Health related Quality of life - child	Kidscreen-10 parent version	T0 T6 T12 T18
Psychological distress	MHI-5	T0 T6 T12 T18
Parenting stress	PSQ-S	T0 T6 T12 T18
Treatment satisfaction	4 questions based on the Jeugdthermometer parent version	T0 T6 T12 T18

367

368 Table 1. Overview of outcome assessments.

369

370 1. Clinician ratings

371 *Daily functioning.* The Dutch version of the HoNOSCA[56] will be used to measure mental
 372 health symptoms and daily functioning. Items are rated on a 5-point scale indicating the
 373 severity of problems ranging from no problem (0) to severe problem (4). Studies
 374 demonstrated sufficient reliability and validity for use in clinical samples [56-58].

375 *Socio-demographics and general caseload information.* Mental health workers provide
 376 information about the patients' level of completed education, referrer, admission duration
 377 and whether IQ tests has been conducted. Mental health care workers also complete
 378 questions about the size and composition of the caseload as part of the audit procedure.

379 *Content of care.* Content of care encompasses 7 multiple-choice questions that provides
 380 insight into type of treatment and support, frequency of visits, and frequency of provided
 381 intensive 'ACT' care in the past 6 months.

382

383 2. Self-report

384 *Psychosocial well-being.* The Strengths and Difficulties Questionnaire (SDQ) is a brief
 385 screening questionnaire for children and adolescents which screens for psychosocial well-

1
2
3 386 being[59, 60]. It includes 20 questions measuring the subscales emotional-, conduct-, and
4
5 387 hyperactivity/inattention symptoms and peer problems. The subscale prosocial behaviour
6
7 388 is excluded, because scores of this subscale are not necessary to compute a total difficulties
8
9 389 score. Each item is scored on a 3-point scale (0 = not true, 1 = somewhat true, and 2 =
10
11 390 certainly true). The subscales are ranging from 0 to 10 for each scale and are added
12
13 391 together to generate a total difficulties score, ranging from 0-40. Scores above the cut-off
14
15 392 of 16 (> 90th percentile) are considered 'abnormal'[59, 61]. In addition, if an adolescent
16
17 393 experiences difficulty, the impact scale can be used to indicate the extent to which any
18
19 394 problems interfere with daily functioning. The 5 items are scored on a 3-point scale (0 =
20
21 395 not at all/only a little, 1 = quite a lot, 2 = a great deal) and can be added to compute an
22
23 396 impact score that ranges from 0 to 10. Scores above the cut-off of 2 are considered
24
25 397 'abnormal'[59, 61]. The SDQ was found to have sufficient reliability and validity for
26
27 398 assessment in clinical samples[59, 60, 62-64].

29 399 *Health related Quality of Life.* The Kidscreen-10 is a 10-item questionnaire measuring
30
31 400 health related quality of life[65, 66]. Items are rated on a 5-point Likert scale ranging from
32
33 401 0 (never) to 5 (always). A total score can be generated by summing the 10 items. Total
34
35 402 scores will be converted into Rasch-scores[67] and translated into T-values (M = 50; SD
36
37 403 = 10), with higher values indicating higher health related quality of life. In addition to these
38
39 404 10 brief questions, the adolescents will be asked to provide additional information
40
41 405 concerning important areas of daily living needs, such as finance, education or housing.
42
43 406 Research has shown adequate psychometric properties for the he Kidscreen-10[66].

45 407 *Depressive symptoms.* Depressive symptoms will be measured using the Dutch version of
46
47 408 the Child Depression Inventory-2 (CDI-2)[68, 69]. The CDI-2 consists of 28 items
48
49 409 measured on a 3-point scale ranging from 0 (depressive symptom is absent) to 2
50
51 410 (depressive symptom is always present). Sum scores can be computed by adding together
52
53 411 scores of all 28 items. A higher total score means more depressive symptoms. A total score
54
55 412 of 14 or higher indicates clinical levels of depressive symptoms[68]. The internal
56
57 413 consistency and validity of the CDI-2 have shown to be good[68].

59 414 *Social support.* To measure social support, the scale 'Social support and peers' from the

1
2
3 415 Kidscreen-52[67] will be used. This scale examines the quality of the social interaction
4
5 416 between adolescents using six items, for example, 'did you have fun with friends?'. The
6
7 417 items are measured on a 5-point Likert scale ranging from 1 (never) to 5 (always). A total
8
9 418 subscale score can be computed by adding the 6 items. The total score will then be
10
11 419 converted into Rasch-scores and translated into T-values (M = 50; SD = 10), with higher
12
13 420 values indicating higher quality of social interaction with peers[67]. We added two
14
15 421 additional questions about satisfaction with social support. The KIDSCREEN-52 has shown
16
17 422 acceptable levels of reliability and validity[70, 71].

18
19 423 *Empowerment.* Empowerment will be measured with the subscale 'interactional
20
21 424 empowerment' from the questionnaire EMPO 3.1[72, 73], which assesses the willingness
22
23 425 to change undesired situations, to look for solutions, to take control and to know how to
24
25 426 access resources[73]. The subscale comprises 6 questions measured on a 5-point Likert
26
27 427 scale ranging from 1 (strongly disagree) to 5 (strongly agree). A total score can be
28
29 428 computed by summing the 6 items and can then be translated into T-values, with higher
30
31 429 values indicating higher level of empowerment. According to the authors of the EMPO
32
33 430 3.1[72] the questionnaire shows good internal consistency in a large clinical sample (total
34
35 431 scale $\alpha = .89$; subscale intrapersonal empowerment $\alpha = 0.89$; subscale interactional
36
37 432 empowerment $\alpha = 0.79$).

38
39 433 *Psychosis risk screening.* The Prodromal Questionnaire (PQ-16)[74] is a self-report
40
41 434 questionnaire used to screen for subclinical psychotic symptoms that may indicate an
42
43 435 increased risk of psychotic disorder in the future. It consists of 16 items that can be rated
44
45 436 as true (1) or false (0), based on subjective experiences during the previous month. If
46
47 437 true, the distress score will be measured on a 4-point Likert scale ranging from 0 (no
48
49 438 distress) to 3 (severe distress). Total score on the PQ-16 can be calculated by adding up
50
51 439 all items, ranging from 0-16. A cut-off score of ≥ 6 predicts a high risk status with high
52
53 440 sensitivity (87%) and specificity (87%)[74]. Research has shown good psychometric
54
55 441 properties for the PQ-16[74-76].

56
57 442 *Treatment satisfaction.* Satisfaction with treatment will be measured with four brief
58
59 443 questions based on the Jeugdthermometer[77]. Treatment satisfaction is rated on a scale

1
2
3 444 from 1 (very bad) to 10 (very good).
4

5 445 *Care utilization.* At baseline assessment, patients will report their previous care utilization
6
7 446 via a single multiple choice question.

8
9 447 *Care utilization and coordination.* At follow-up, patients will report which forms of care they
10
11 448 receive in addition to Youth Flexible ACT. In addition, they will report their satisfaction
12
13 449 between the cooperation with the Youth Flexible ACT team and other health care facilities
14
15 450 on a scale from 1 (unsatisfactory) to 10 (very satisfactory).
16

17 451

18 19 452 3. Parent-report

20
21 453 *Psychosocial well-being.* The SDQ-P (Strengths and Difficulties Questionnaire) is the parent
22
23 454 version of the SDQ, as described above[59]. The 20-item total difficulties subscale are
24
25 455 allocated to 4 domains: emotional symptoms, conduct problems, hyperactivity-inattention
26
27 456 and peer problems. Parents rate the items on a 3-point Likert scale, ranging from 0 (not
28
29 457 true) to 2 (certainly true). Scale scores can be computed by summing the scores on the
30
31 458 scale items (range 0–10). A total difficulty score can be computed by adding the 4 scale
32
33 459 scores (range 0–40). Scores above the cut-off of 14 (> 90th percentile) are considered as
34
35 460 a raised level of psychosocial problems[59, 78]. Studies showed good psychometric
36
37 461 properties of the SDQ-P[60, 78, 79].

38
39 462 *Health related Quality of Life.* The Kidscreen-10 parent report is the parent-version of the
40
41 463 Kidscreen-10, a 10-item questionnaire on quality of life, as described above[66, 67].

42
43 464 *Psychological distress.* The Mental Health Inventory (MHI-5)[80] is a brief questionnaire
44
45 465 and will be used to assess parental psychological distress. The MHI-5 consists of 5 items
46
47 466 scored on a 6-point Likert scale ranging from 0 (all of the time) to 5 (none of the time).
48
49 467 The total score will be obtained by summing up recoded scores, and transforming the
50
51 468 scores to a scale ranging from 0 to 100. A higher score indicates better mental health and
52
53 469 lower psychological stress levels. An MHI-5 cut-off score of ≤ 60 will be used to indicate
54
55 470 psychological distress[81]. The MHI-5 has shown good psychometric properties[82-85].

56
57 471 *Parenting Stress.* Parenting stress will be measured using the short version of the Parenting
58
59 472 Stress Questionnaire (PSQ-S)[86]. The questionnaire focuses on the quality of the parent-

1
2
3 473 child relationship measured using 10 items rated on a 4-point scale ranging from 1 (is
4 474 completely applicable to me) to 4 (is not applicable to me). A total score will be calculated
5 475 by summing all recoded items (ranging 10-40) with higher total scores indicate higher
6 476 levels of parental stress. Scores higher than 22 reflect raised level of parenting stress.
7 477 Research has shown sufficient psychometric properties[73, 86, 87].

8 478 *Treatment satisfaction.* Satisfaction with treatment will be measured using 4 brief
9 479 questions based on the Jeugdthermometer parent version[77]. The items are rated on a
10 480 scale from 1 (very bad) to 10 (very good).

11 481
12 482 4. Youth Flexible ACT model fidelity

13 483 The association between psychosocial functioning of adolescents and (elements of) model
14 484 fidelity will be studied. The level of implementation of the model will be measured with the
15 485 Youth Flexible ACT scale (Youth FACTs) developed by the Centre for Certification ACT and
16 486 Flexible ACT (CCAF) in 2014[42]. The CCAF was established in the Netherlands in 2008 by
17 487 Dutch mental health care professionals and researchers to ensure the quality of ACT and
18 488 Flexible ACT. During the Youth Flexible ACT Study each team will be subjected to a single
19 489 and official audit performed by the CCAF. These audits determine the degree to which each
20 490 team complies with the Youth Flexible ACT model. All teams will be audited within a period
21 491 of 1.5 years. The Youth FACTs consists of 62 items measuring 7 main elements: team
22 492 structure (15 items), team process (12 items), diagnostics, treatment and interventions
23 493 (12 items), organization of services (11 items), community care (5 items), monitoring (3
24 494 items), and level of professionalization (4 items). Two independent raters from CCAF will
25 495 score the Youth FACTs on a five-point rating scale ranging from 1 (minimum
26 496 implementation) to 5 (maximum implementation). The CCAF defines a total score on the
27 497 Youth FACTs of 3.0 and lower as insufficient implementation while scores between 3.1 and
28 498 3.3 indicate a temporary certificate for 1 year, with improvements to be made to obtain a
29 499 final certificate. Scores 3.4 to 4.0 are sufficient to receive the certificate while scores of
30 500 4.1 and higher are regarded as excellent. If a team has received a certificate, it remains
31 501 valid for three years. During this period, the team is expected to report any major changes,

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2
3 502 including reorganizations and divisions, to the CCAF.
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5 503

6
7 504 5. Administrative data
8

9 505 Socio-demographic and clinical characteristics (sex, age, psychiatric diagnose, treatment
10 duration) will be collected via electronic patient records.
11
12

13 507

14 508 **Statistical analysis**

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16
17 509 Latent Growth Curve Analysis will be used to examine change in psychosocial functioning
18 over time (T0, T6, T12, T18 in months) and its relation to model fidelity. We hypothesize
19 510 that (1) psychosocial problems will decrease while treated by a Youth Flexible ACT team
20 511 and (2) higher Youth Flexible ACT model fidelity will lead to greater improvements in
21 512 psychosocial functioning over time. This change over time will be calculated with growth
22 513 parameters (intercept, linear slope and possible quadratic factor) for each patient. For each
23 514 of the study outcomes, the best fit function (model) will be assessed to measure change
24 515 in outcomes. Control variables (age, gender and psychiatric diagnoses of patients) will be
25 516 included as covariates in the growth model. In addition, the multiple elements of model
26 517 fidelity will be used as predictors of the growth parameters. Regression coefficients will
27 518 indicate the extent to which these elements contribute to these parameters. To deal with
28 519 missing values, the Full Information Maximum Likelihood estimator, or the using-all-
29 520 available information method, will be used.
30 521

31 522 Furthermore, the data will be clustered within subjects and teams. Seven mental
32 523 health institutions will participate in the study, with a total of 16 teams and an expected
33 524 average of 20 patients per team. If the results of this study demonstrate substantial
34 525 variation between the participating teams, analysis will be performed to account for team
35 526 effects.
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44 528 **Sample size calculation**

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47 529 Given the practical challenges in conducting a multicentre study with a complex
48 530 intervention, the aim of this study is to achieve maximum participation[88]. A power

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3 531 analysis for a paired t-test with G*power indicated that a minimum of 156 patients will
4
5 532 have to be recruited to achieve a power of 0.80, an alpha of 0.05, and an effect size of
6
7 533 0.20 (one-tailed). Slightly more patients will be required (n = 165) for a small slope effect
8
9 534 of a linear latent growth model[89]. When accounting for missing values, a target sample
10
11 535 size of 200 participants should be sufficient. The past inflow data of all participating Youth
12
13 536 Flexible ACT teams show that approximately 500 patients are included in care every year.
14
15 537 This indicates that a sample size of 200 is attainable. Concerning follow-up measurements,
16
17 538 the included teams indicated that most patients finish their Youth Flexible ACT treatment
18
19 539 in 1 to 2 years. This suggests that most of the participants will remain in Flexible ACT care
20
21 540 for the duration of the study (i.e. 1.5. years). We expect being able to continue collecting
22
23 541 data on most of these participants through follow-up assessments. The participating teams
24
25 542 estimated that less than 5% of patients drop-out of Youth Flexible ACT care entirely. To
26
27 543 ensure that the sample size is reached, minimum number of inclusions are determined for
28
29 544 each team. In addition, each team strives for maximum inclusion beyond this minimum
30
31 545 bound.

32 546

33 547

34 548 **DISCUSSION**

35 549 **Preliminary reflection on the limitations and strengths of the design**

36 550 The observational and naturalistic character of the study design is both its weakness and
37 551 its strength. Conclusions are restricted to associations between Youth Flexible ACT care
38 552 and treatment outcome with the obtained data. No causal relationships can be implied
39 553 because a control group is absent. Realizing a resembling control group and providing them
40 554 treatment as usual is practically impossible to achieve, due to the complexity of the
41 555 psychosocial problems, vulnerability to mental health crisis and an extensive avoidance of
42 556 mental health services. Additionally, as it is difficult to find a resembling study population,
43 557 it is not possible to match the research results with a data set of another comparable cohort
44 558 study. Furthermore, as a consequence of a naturalistic study design, the data obtained in
45 559 the practical field of mental healthcare is subject to transitions and developments during

1
2
3 560 data collection (e.g., changes in team structure).
4

5 561 Nevertheless, an important strength of the current study is its strong external
6
7 562 validity, as Youth Flexible ACT will be studied as it is used in daily practice[90]. Another
8
9 563 strength of the study is its longitudinal design with follow-up assessments up to 18 months,
10
11 564 providing the opportunity to evaluate long-term effects. Furthermore, examining a broad
12
13 565 set of outcomes (both psychiatric and social functioning) allows for a more complete view
14
15 566 of Youth Flexible ACT, since the data on participant and service characteristics will be
16
17 567 collected from a large sample of patients and mental health workers.
18

19 568

20 21 569 **Implications for clinical practice**

22
23 570 When adolescents experience complex problems affecting various aspects of their lives,
24
25 571 fragmentation of care services can lead to inconsistent and ineffective care. Youth Flexible
26
27 572 ACT actively engages adolescents in treatment and provides a flexible response to the
28
29 573 needs in different stages of care that enhances continuity of care. By providing assertive
30
31 574 and integrated treatment, Youth Flexible ACT aims to tackle this fragmented mental health
32
33 575 care system. The present study will contribute to clinical practice by providing insights into
34
35 576 the effectiveness of Youth Flexible ACT and the essential elements responsible for the
36
37 577 effect. This will provide valuable information for mental health care organizations, funding
38
39 578 organizations, and policymakers on how to maximize the quality of care for a vulnerable
40
41 579 group of adolescents for whom the existing regular outpatient mental healthcare is hardly
42
43 580 suitable.
44

45 581

46 47 582 **ETHICS AND DISSEMINATION**

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49 583 The medical ethics committee CMO Region Arnhem-Nijmegen in the Netherlands concluded
50
51 584 that the present study (NL57443.091.16) does not require medical ethical approval. In
52
53 585 addition, this study received ethical approval by Trimbos ethics committee (201607_75-
54
55 586 FACT2). The Trimbos Institute is the Netherlands Institute of Mental Health and Addiction,
56
57 587 a non-profit research and knowledge centre that reviews non-WMO research projects. This
58
59 588 committee ruled that our protocol complies with all applicable regulations. This approval

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2
3 589 applies for all participating institutions. Written informed consent from adolescents and
4
5 590 parents or legal guardians will be obtained. The results of the study will be reported in
6
7 591 accordance with the STROBE Statement. Results will be disseminated via peer-reviewed
8
9 592 academic journals and presentations at conferences. In addition, results will be made
10
11 593 available for participating sites, funders and researchers.

12
13 594

14 15 595 **AUTHOR CONTRIBUTIONS**

16
17 596 MB will be responsible for data collection and data analysis as well as for reporting the
18
19 597 study results. AV will support the data analysis. DC, NF, and HK read the manuscript and
20
21 598 provided suggestions for improvement. DC, NF, and HK also serve as supervisors. All
22
23 599 authors read and approved the final manuscript.

24
25 600

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28
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30
31 603 foundation aimed at improving the quality of mental health care in the east part of North
32
33 604 Brabant, the Netherlands. The Olim Foundation provided the funding after reviewing and
34
35 605 approving the present protocol. The Olim Foundation has no role in the collection, analysis
36
37 606 and interpretation of data, or in the writing of manuscripts. Additionally, each of the six
38
39 607 participating institutions will pay a small contribution of €7600,- to cover research material
40
41 608 expenses including online data managing systems. Finally, the Trimbos Institute will
42
43 609 provide the necessary research expertise.

44
45 610

46 47 611 **COMPETING INTERESTS**

48
49 612 None declared.

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For peer review only

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract Title, page number 1 (b) Provide in the abstract an informative and balanced summary of what was done and what was found Abstract, page number 3
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported Introduction, page numbers 5-9
Objectives	3	State specific objectives, including any prespecified hypotheses Introduction, page numbers 9-10
Methods		
Study design	4	Present key elements of study design early in the paper Methods, page numbers 9-10
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection Methods, page numbers 9-11
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Methods, page numbers 10-11 (b) For matched studies, give matching criteria and number of exposed and unexposed N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable Methods, page numbers 14-20
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group Methods, page numbers 14-20
Bias	9	Describe any efforts to address potential sources of bias Discussion, page numbers 14-20
Study size	10	Explain how the study size was arrived at Methods, page numbers 20-21
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why N/A (study protocol)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding Methods, page number 20 (b) Describe any methods used to examine subgroups and interactions Methods, page number 20 (c) Explain how missing data were addressed Methods, page number 20 (d) If applicable, explain how loss to follow-up was addressed Methods, page number 20 (e) Describe any sensitivity analyses N/A (study protocol)

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed <i>Methods, page numbers 20-21</i>
		(b) Give reasons for non-participation at each stage <i>N/A (study protocol)</i>
		(c) Consider use of a flow diagram <i>N/A (study protocol)</i>
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders <i>N/A (study protocol)</i>
		(b) Indicate number of participants with missing data for each variable of interest <i>N/A (study protocol)</i>
		(c) Summarise follow-up time (eg, average and total amount) <i>N/A (study protocol)</i>
Outcome data	15*	Report numbers of outcome events or summary measures over time <i>N/A (study protocol)</i>
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included <i>N/A (study protocol)</i>
		(b) Report category boundaries when continuous variables were categorized <i>N/A (study protocol)</i>
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period <i>N/A (study protocol)</i>
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses <i>Methods, page number 13</i>
Discussion		
Key results	18	Summarise key results with reference to study objectives <i>N/A (study protocol)</i>
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias <i>Discussion, page numbers 21-22</i>
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence <i>N/A (study protocol)</i>
Generalisability	21	Discuss the generalisability (external validity) of the study results <i>Discussion, page numbers 21-22</i>
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based <i>Funding, page number 23</i>

*Give information separately for exposed and unexposed groups.

1 **Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and
2 published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely
3 available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at
4 <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is
5 available at <http://www.strobe-statement.org>.
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