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# BMJ Open

## Mediators and theories of change in psychotherapy with adolescents: a systematic review protocol

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# Mediators and theories of change in psychotherapy with adolescents: a systematic review protocol

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## 20 21 22 23 **Abstract**

### 24 25 26 27 Introduction

28  
29 Approximately, 75% of mental disorders emerge before the age of 25 years but less than half  
30  
31 receive appropriate treatment. Little is known about the mechanisms underlying the therapeutic  
32  
33 change of adolescents in psychotherapy. The “European Network of Individualized  
34  
35 Psychotherapy Treatment of Young People with Mental Disorders” (TREATme), funded by the  
36  
37 European Cooperation in Science and Technology (COST), will conduct the first systematic  
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39 review to summarize the existing knowledge on mediators and theories of change in  
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41 psychotherapy for adolescents.

### 42 43 Method

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45 A systematic review will be conducted, conforming to the reporting guidelines of the Preferred  
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47 Reporting Items for Systematic Reviews and Meta-Analyses statement recommendations.  
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49 Electronic databases (PubMed, PsycINFO) will be systematically searched for prospective,  
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51 longitudinal, and case–control designs which examine mediators of change in psychotherapy for  
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53 adolescents.

### 54 55 56 57 58 59 60 Ethics and dissemination

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3 Ethical approval is not required for this systematic review as no primary data will be collected.  
4 The results will be published in a peer-reviewed journals and at conference presentations and will  
5 be shared with stakeholder groups. The whole data set will be offered to other research groups  
6 following recommendations of the open science initiative. Databases with the systematic search  
7 will be made openly available following open science initiatives.  
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## Strengths and Limitations

- Review aims at identifying underlying mechanisms of change in the process of psychotherapy for adolescents
- Reviewers are from a European multidisciplinary researcher network with researchers and clinicians from 30 countries
- First comprehensive overview of mediators in psychotherapy with adolescents
- Broad inclusion criteria increase external validity but limits the possibility of causal conclusions Including non-Randomised-Controlled-Trials studies, it is likely not feasible to estimate aggregated effect sizes for the identified mediators.

## Introduction

Adolescents and young adults are a particularly important and vulnerable group with distinct mental health needs. According to Kessler and colleagues, 50% of lifetime diagnosable mental health disorders start by the age of 14, and this number increases to 75% by the age of 25.[1, 2] Ignoring young people's mental health needs can result in long-lasting adverse developmental outcomes for the individual and the society. These include psychiatric disorders in adulthood, impaired social functioning, difficulties with employment, as well as poorer general health outcomes.[3]

Psychotherapy is effective, efficient, and cost-effective, providing long-term impacts which are not possible with psychopharmacological treatment alone.[4, 5, 6] There is strong evidence on the general effectiveness of psychotherapy for treating mental disorders in adolescents,[7, 8] and a wealth of psychotherapy treatment modalities are currently being used and researched, with more than 550 different psychotherapy models that can be applied for the young.[9] Treatment response is explained by different mechanisms of change and accounted for by a variety of mediators (e.g. self-reflection, learning compensatory skills, changing automatic thoughts, etc.) associated with each different treatment modality. While various psychotherapy modalities (e.g. Psychodynamic Psychotherapy (PDT); Cognitive Behavioural Therapy (CBT)) have shown equally good treatment outcomes overall, adherence to a specific treatment modality has not shown to significantly impact the outcome in child and adolescent psychotherapy.[10] However, to understand therapeutic change and enhance outcomes, it is necessary to identify treatment processes or characteristics within the therapist, the adolescent, parent or family that facilitate successful therapeutic change and isolate those that are redundant and can be dismissed.[9]



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3 Thus, research on underlying specific mechanisms of change across treatment modalities and  
4 settings is essential to optimizing treatment.  
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7 An important first step towards examination of mechanisms of change in psychotherapy is the  
8 identification of mediators. While moderators (e.g. gender, age) serve to clarify what kind of  
9 treatment is adequate for a specific person under certain circumstances, mechanisms of change  
10 define causal relationships between therapeutic change and psychological interventions. A  
11 mechanism of change explains how an intervention translates into a process that leads to an  
12 outcome, e.g. change in symptoms.[11] Thus, a mechanism is an explanatory concept that can  
13 be investigated by researching mediators, i.e., variables that explain changes statistically. Kazdin  
14 has formulated clear criteria on how to assess mediators of psychological treatments:[12]  
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- 21 ● Conduct sufficiently powered randomized clinical trials
- 22 ● Use valid and reliable measures for mediators that are sensitive to change
- 23 ● Apply a process design in which changes of the mediator temporally precede changes in  
24 therapeutic outcome and the mediator variable is measured repeatedly
- 25 ● Compare mediators that are theory-driven with non-specific mediators
- 26 ● Apply different dosages to prove that a stronger mediator-change leads to more  
27 therapeutic changes
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33 However, even after 13 years of Kazdin's suggestions of how to assess mechanisms of change  
34 in psychotherapy research,[12] there is still an alarming lack of studies, inconclusive results (e.g.  
35 the treatment of depression in adults)[13] and very little research on change mechanisms for the  
36 treatment of adolescents.[14, 15] Cuijpers et al. conclude that after more than 70 years of  
37 systematic psychotherapy research, we have no empirically validated mechanisms of change in  
38 adult psychotherapy.[16] The current systematic review is the first to summarize the existing  
39 knowledge on mediators and theories of change in psychotherapy for adolescents.  
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45 To address these challenges related to mediators and measures of the mechanisms of change  
46 and therapies' efficacy in children and adolescents besides other activities, the European  
47 Cooperation in Science and Technology (COST) funded a 4-year program named "European  
48 Network of Individualized Psychotherapy Treatment of Young People with Mental Disorders" with  
49 the acronym TREATme ([www.treat-me.eu](http://www.treat-me.eu)) that serves as a European multidisciplinary  
50 researcher network with researchers and clinicians from 30 countries. TREATme reviews the  
51 academic research relating to mechanisms of change in patients aged between 12 and 30 years  
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3 receiving psychological treatments. For the current review, a part of the collected data set was  
4 used using only data concerning adolescents. The aim is to provide an overview of existing  
5 research on psychological factors that mediate psychotherapeutic change in adolescents. We will  
6 conduct a narrative synthesis of all studies available up to 2020. The objectives of this review are  
7 the following:  
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- 10  
11 1. To identify which mediators and theories of change have been studied in psychotherapy  
12 with adolescents
- 13 2. To identify if there are adolescence-, disorder- or treatment-specific mediators
- 14 3. To critically evaluate the methodological approach of the current research data available  
15 on mediators in psychotherapy with adolescents  
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21 In order to obtain a comprehensive overview of the field of psychotherapy with adolescents, we  
22 will include various forms of psychotherapy and quantitative research designs. We will select all  
23 studies including a statistical test of mediation (e.g. Baron & Kenny or more advanced  
24 methods)[17] and will summarise study characteristics as well as results and discuss the extent  
25 to which these studies meet the most important requirements for mediator research that were  
26 mentioned earlier. Furthermore, we will relate mediators to the respective change theories and  
27 describe which mediators successfully explained therapeutic change. Ultimately, this review can  
28 contribute to the challenging process of identifying underlying mechanisms of change in the  
29 process of psychotherapy for adolescents.  
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## 40 **Method**

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42 The review was registered in Prospero (under review) and follows the Preferred reporting items  
43 for systematic review and meta-analysis protocols (PRISMA-P)[18]. This article is based upon  
44 work from the COST (European Cooperation in Science and Technology) Action “European  
45 Network of Individualized Psychotherapy Treatment of Young People with Mental Disorders”  
46 (TREATme) aiming to improve knowledge and understanding of psychotherapeutic  
47 interventions in young people. The PICO model was used to define the research question.  
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## 53 **Eligibility criteria**

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3 Studies from any geographical location, written in English, available as full-text and published  
4 from inception onwards until February 1, 2020 that meet criteria, will be included in the review.  
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6 Grey literature such as theses, dissertations or conference proceedings will also be included.  
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## 11 **Types of studies**

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15 Due to a lack of studies fulfilling all criteria for mediator research, we decided to include a broad  
16 range of study types. Studies will be selected if they include statistical analysis of mediators in  
17 psychotherapy. This comprises a) empirical quantitative studies following prospective,  
18 longitudinal, and case-control designs, which include b) terms related to or describing mediators,  
19 and c) include a psychosocial intervention and/or psychotherapeutic intervention or treatment for  
20 primary/ secondary prevention.  
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## 26 **Types of participants**

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28 The World Health Organization (WHO) defines adolescents as individuals between 10 and 19  
29 years of age,[19] which was also the age group selected for our inclusion criteria. These  
30 participants would have to suffer from a mental disorder (e.g. depression, eating disorders) or  
31 psychological difficulties (e.g. binge drinking) and receive a psychotherapeutic intervention,  
32 including primary and secondary prevention programs. All comparators will be included as we will  
33 investigate mediators in all treatments and not the efficacy of one treatment over another.  
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## 39 **Types of interventions**

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42 Studies will be included if they report an intervention aimed at preventing, ameliorating and/or  
43 treating psychological problems of adolescents by using psychosocial mechanisms and strategies  
44 in any setting (i.e., individual, family, group, inpatients, eMental health, etc.). These interventions  
45 should not be primarily biological or physiological. Examples of interventions include all branches  
46 or types of psychotherapy: psychodynamic, integrative, systemic, cognitive-based or cognitive-  
47 behavioural, interpersonal, humanistic (such as emotion-focused, supportive, motivational  
48 interviewing), psychoeducation and third-wave approaches (such as mindfulness-based  
49 therapies).  
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## 56 **Search strategy**

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3 The search strategy includes terms relating to or describing the intervention. These terms have  
4 been combined with the Cochrane MEDLINE filter for controlled trials of interventions and were  
5 adapted for PsycINFO.[20] Studies published from inception to 01.02.2020 have been sought.  
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7 The search string can be found in the online supplementary.  
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## 10 **Data extraction**

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13 Study selection will be carried out by a group of 20 experienced researchers divided into ten pairs  
14 who will independently assess the eligibility of studies retrieved using the search strategy in two  
15 phases. The first phase comprises the screening of the titles and/or abstracts of studies that  
16 potentially meet the inclusion criteria outlined above. In the second phase, each pair of reviewers  
17 will evaluate the full text of these potentially eligible studies to see if they meet the inclusion  
18 criteria. Disagreements will be discussed by the pair, and a third reviewer will be involved if  
19 consensus cannot be reached. Finally, a fourth independent reviewer will perform an additional  
20 quality control check by assessing the eligibility of every fifth excluded study. Disagreements at  
21 this stage will be solved through discussion with the original review pair.  
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29 Data records will be managed with the support of Microsoft Excel.[21] A standardised form will be  
30 used to extract the information for the review. Extracted information will include: study setting;  
31 study population, participant demographics and baseline characteristics; details of the  
32 intervention and control conditions; study methodology; outcomes and times of measurement;  
33 assessed mediators; type of mediation analysis; information for assessment of the risk of bias.  
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35 Two review authors will extract information independently; discrepancies will be identified and  
36 resolved through discussion or with a third author where necessary.  
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## 41 **Critical appraisal**

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44 Although no standard form for evaluating mediation studies has been established, studies will be  
45 checked against general criteria for identifying mediators of psychosocial interventions in  
46 research, such as summarized by Kazdin and Lemmens et al.[12,13].  
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## 50 **Data synthesis**

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52 We will provide a narrative synthesis of the findings from the included studies, with focus on the  
53 categories of mediators that have been tested, types of psychosocial interventions that have been  
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3 investigated, and mental disorders or psychological difficulties of adolescents that have been  
4 treated. It will be discussed if age-, disorder- or treatment-specific mediators can be identified.  
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## 7 **Outcomes and prioritization**

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10 The primary outcome will be mediators related to change in mental problems or disorders in  
11 adolescents measured by any already validated instrument or tool made for that purpose. Data  
12 on the disorder, to the degree available, will be categorised into depression, anxiety, substance  
13 misuse, externalising problems, severe mental illness (e.g. psychosis, bipolar disorder) and  
14 others (e.g. eating disorders). The therapies will be categorised into: psychodynamic, integrative,  
15 systematic, cognitive-based or cognitive-behavioural, interpersonal, humanistic,  
16 psychoeducation, and third-wave. Mediators and instruments for assessing them will be identified.  
17 Statistical analyses for evaluating the effect of mediators will be recorded. Pre-treatment and post-  
18 treatment scores will be recorded, and the differences compared.  
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## 26 **Risk of bias in individual studies**

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28 The Mixed Methods Appraisal Tool will be used to evaluate the overall study quality using a formal  
29 risk of bias assessment.[22] It permits appraisal of the methodological quality of five categories  
30 of studies: qualitative research, randomized controlled trials, non-randomized studies,  
31 quantitative descriptive studies, and mixed methods studies.  
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## 36 **Patient and Public Involvement**

37 No patient was involved in planning and conducting the study.  
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## 41 **Discussion**

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44 As far as the authors are aware, this is the first systematic review of its kind, assessing mediators  
45 of psychotherapeutic changes in adolescents. The findings will inform how much is currently  
46 known about such mediators and the practical implications of this knowledge for treatment  
47 planning and outcomes. The results will also shed light on how these empirically studied  
48 mediators correspond with the theoretically putative mechanisms of change in particular models  
49 of intervention. Using qualitative synthesis, we will evaluate and comment on the conclusiveness  
50 of age-, disorder-, or treatment-specific-mediators and map out most pressing needs for future  
51 research on mediators and mechanisms of change in adolescent psychotherapy. The review will  
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3 provide a base for comparing our results with those of systematic reviews of adults to assess  
4 whether there are similar or different mediators in adolescents explaining therapeutic change.  
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7 The strengths of this protocol include the gathering of a large multidisciplinary group of  
8 international researchers with long-standing accumulated experience in the area that has worked  
9 on this topic for three years by regular online and face to face meetings. Furthermore, the group  
10 has consulted international experts in the field to develop the protocol. A structured quality  
11 assurance will be carried out as well as several search updates to ensure the completeness of  
12 the data set. The whole data set will be offered to other research groups following the  
13 recommendations of the open science initiative.  
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19 Limitations of this protocol include the use of broad inclusion criteria to describe the existing  
20 knowledge comprehensively and increase external validity, which likely limits the possibility of  
21 causal conclusions by also including non-Randomised-Controlled-Trials studies. For the same  
22 reason, it is likely not feasible to estimate aggregated effect sizes for the identified mediators. Our  
23 conclusions on mechanisms of change will only be related to empirical quantitative studies as we  
24 have excluded qualitative and theoretical studies. As there is no generally accepted gold standard  
25 for mediation analysis, we expect much variance in the studies, which could lead to our results  
26 being inconclusive or inconsistent. Also, we are analyzing both subclinical conditions and  
27 diagnosable disorders, as well as intervention and prevention studies, which may lead to less  
28 consistent or coherent results, however we will aim report the results separately, establishing  
29 independent conclusions. This was done to address the adolescent age group holistically. As the  
30 rater team consists of a fairly large group, inter-rater bias has to be strictly monitored, and so a  
31 fourth independent reviewer will be introduced to perform additional quality control checks.  
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## 41 a. Contributorship statement

42 All co-authors provided a substantial contribution to the conception and design of the work by  
43 developing the research question, the search string and carrying out the stage 1 screening. The  
44 current manuscript was drafted by the first and second as well as the last author and was  
45 corrected and finally approved by the other authors. All authors agree to be accountable for all  
46 aspects of the work in ensuring that questions related to the accuracy or integrity of any part of  
47 the work are appropriately investigated and resolved.  
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## b. Competing interests

There are no competing interests.

## c. Funding

This article is based upon work from COST Action TREATme (CA 16102), supported by COST (European Cooperation in Science and Technology) ([www.cost.eu](http://www.cost.eu)).

## d. Data sharing statement

After publication of the finale review the data set including our search results and first as well as second stage screening process will be made publicly available for other researchers in a controlled repository.

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41 adolescent OR adolescent\* OR "emerging adulthood" OR "young" OR "juvenile" OR "early adulthood"  
 42 OR "young adulthood" OR "young adult" OR "young adults" OR "teen\*" OR "youth\*" OR "yest" OR  
 43 "juvenil\*" OR "young\*" OR "subadult" OR "immature" OR "adolescen\*" OR "puberty" OR "pubertal" OR  
 44 "puberal" OR DE "Emerging Adulthood" OR DE "Puberty" OR DE "Adolescent Development" OR DE  
 45 "Adolescent Characteristics" OR DE "Adult Development"  
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 51 "psychosocial treatment" OR "psychological intervention\*" OR "psychosocial intervention\*" OR  
 52 psychoeducation OR "group therap\*" OR "family therap\*" OR "general psychiatric management" OR  
 53 GPM OR MA "Mind-Body Therapies" OR "supportive psychotherapy" OR DE "Psychotherapy" OR DE  
 54 "Counseling" OR DE "Psychoeducation" OR DE "Psychosocial Readjustment" OR DE "Psychotherapeutic"  
 55 OR DE "Group Psychotherapy" OR DE "Family Therapy" OR DE "Creative Arts Therapy" OR DE "Mind Body  
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3 Therapy" OR DE "Dance Therapy" OR DE "Art Therapy" OR DE "Play Therapy" OR DE "Supportive  
4 Psychotherapy"

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6 "cbt" OR "cognitive therapy" OR "behavior therapies" OR "behavior therapy" OR "behavioural  
7 treatment" OR "behavioral treatment" OR "behavioral activation" OR "exposure and response  
8 prevention" OR "exposure with response prevention" OR (exposure AND "response prevention") OR  
9 REBT OR "problem solving therapy" OR "interpersonal therapy" OR "mindfulness" OR psychodynamic OR  
10 "psychodynamic therapy" OR DE psychoanalysis OR "psychoanalysis" OR "psychoanalytic" OR  
11 "mentalization based therapy" OR "mentalization based treatment" OR "MBT" OR "transference focused  
12 therapy" OR "transference focused psychotherapy" OR "metacognitive therapy" OR "metacognitive  
13 treatment" OR "Acceptance and Commitment Therapy" OR "ACT" OR "dialectical behavior therapy" OR  
14 "dialectical behaviour therapy" OR DBT OR "Schema Therapy" OR "Schema-focused Therapy" OR  
15 "Systematic Desensitization" OR "Exposure therapy" OR MA relaxation OR "relaxation" OR DE  
16 biofeedback, psychology OR ("biofeedback" AND "psychology") OR "psychology biofeedback" OR  
17 "biofeedback") OR DE hypnosis OR "hypnosis" OR "Attention bias-modification" OR DE "Cognitive  
18 Behavior Therapy" OR DE "Behavior Therapy" OR DE "Behavioral Activation System" OR DE "Exposure  
19 Therapy" OR DE "Interpersonal Psychotherapy" OR DE "Mindfulness" OR DE "Psychodynamic OR DE  
20 Psychotherapy" OR DE "Psychodynamics" OR DE "Acceptance and Commitment Therapy" OR DE  
21 "Dialectical Behavior Therapy" OR DE "Schema Therapy" OR DE "Systematic Desensitization Therapy" OR  
22 DE "Relaxation Therapy"

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31 (exposure AND "response prevention") OR DE "Cognitive Behavior Therapy" OR DE "Cognitive Behaviour  
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33 "behavioural treatment" OR "behavioral activation" OR "exposure and response prevention" OR  
34 "exposure with response prevention OR "Acceptance and Commitment Therapy" OR "ACT" OR  
35 "dialectical behavior therapy" OR "dialectical behaviour therapy" OR DBT OR "Schema-focused therapy"  
36 OR "schema therapy" OR DE "Cognitive Behavior Therapy" OR DE "Behavior Therapy" OR DE "Behavioral  
37 Activation System" OR DE "Exposure Therapy" OR DE "Acceptance and Commitment Therapy" OR DE  
38 "Dialectical Behavior Therapy" OR DE "Schema Therapy "

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44 OR "interpersonal and social rhythm therapy" OR "IPSRT" OR DE "Interpersonal Psychotherapy"

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46 OR "cognitive training" OR "cognitive remediation" OR DE "Brain Training"

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48 OR "behavioral weight control"

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51 OR ("supportive-expressive" AND ("therapy" OR "program" OR "treatment" OR "intervention\*")) OR DE  
52 „Expressive Psychotherapy“ OR DE „Supportive Psychotherapy“ OR ("insight-oriented" AND ("therapy"  
53 OR "program" OR "treatment" OR "intervention\*")) OR DE „Insight Therapy“ OR "interpretive  
54 psychotherapy" OR (interpretive AND (DE psychotherapy OR ("psychotherapies" OR "psychotherapy")))  
55 OR "General psychiatric management" OR (Systems AND (MA education OR "education" OR "training"

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# BMJ Open

## Mediators and theories of change in psychotherapy with adolescents: a systematic review protocol

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# Mediators and theories of change in psychotherapy with adolescents: a systematic review protocol

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## Abstract

### Introduction

Approximately 75% of mental disorders emerge before the age of 25 years but less than half receive appropriate treatment. Little is known about the mechanisms underlying the therapeutic change of adolescents in psychotherapy. The “European Network of Individualized Psychotherapy Treatment of Young People with Mental Disorders” (TREATme), funded by the European Cooperation in Science and Technology (COST), will conduct the first systematic review to summarize the existing knowledge on mediators and theories of change in psychotherapy for adolescents.

### Method

A systematic review will be conducted, conforming to the reporting guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement recommendations. Electronic databases (PubMed and PsycINFO) have been systematically searched on the 23<sup>rd</sup> of February 2020, for prospective, longitudinal, and case–control designs which examine mediators of change. Participants will be adolescents between 10 and 19 years of age who suffer from a mental disorder or psychological difficulties and receive an intervention that aims at preventing, ameliorating and/or treating psychological problems.

### Ethics and dissemination

Ethical approval is not required for this systematic review as no primary data will be collected. The results will be published in a peer-reviewed journals and at conference presentations and will be shared with stakeholder groups. The whole data set will be offered to other research groups following recommendations of the open science initiative. Databases with the systematic search will be made openly available following open science initiatives. The planned review has been registered in PROSPERO (CRD42020177535).

## Strengths and Limitations

- Review aims at identifying underlying mechanisms of change in the process of psychotherapy for adolescents
- Reviewers are from a European multidisciplinary researcher network with researchers and clinicians from 30 countries
- First comprehensive overview of mediators in psychotherapy carried out with adolescents
- Broad inclusion criteria increase external validity but limits the possibility of causal conclusions including non-randomised controlled trials studies, it is likely not feasible to estimate aggregated effect sizes for the identified mediators.

## Introduction

Adolescents and young adults are a particularly important and vulnerable group with distinct mental health needs. According to Kessler and colleagues, 50% of lifetime diagnosable mental health disorders start by the age of 14, and this number increases to 75% by the age of 25 [1, 2]. Ignoring young people's mental health needs can result in long-lasting adverse developmental outcomes for the individual and society. These include: psychiatric disorders in adulthood, impaired social functioning, difficulties with employment, as well as poorer general health outcomes [3].

Psychotherapy is effective, efficient, and cost-effective, providing long-term impacts which are not possible with psychopharmacological treatment alone [4, 5, 6]. There is strong evidence on the general effectiveness of psychotherapy for treating mental disorders in adolescents [7, 8], and a wealth of psychotherapy treatment modalities are currently being used and researched, with more than 550 different psychotherapy models that can be applied to young people [9]. Treatment response is explained by different mechanisms of change and accounted for by a variety of mediators (e.g. self-reflection, learning compensatory skills, changing automatic thoughts, etc.) associated with each treatment modality. While various psychotherapy modalities (e.g. Psychodynamic Psychotherapy (PDT); Cognitive Behavioural Therapy (CBT)) have shown equally good treatment outcomes overall, adherence to a specific treatment modality has not shown to significantly impact the outcome in child and adolescent psychotherapy [10]. However, to understand therapeutic change and enhance outcomes, it is necessary to identify treatment processes or characteristics within the therapist, the adolescent, parent or family that facilitate successful therapeutic change and isolate those that are redundant and can be dismissed [9].

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3 Thus, research on underlying specific mechanisms of change across treatment modalities and  
4 settings is essential to optimising treatment.  
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7 An important first step towards examination of mechanisms of change in psychotherapy is the  
8 identification of mediators. While moderators (e.g. gender, age) serve to clarify what kind of  
9 treatment is adequate for a specific person under certain circumstances, mechanisms of change  
10 define causal relationships between therapeutic change and psychological interventions. A  
11 mechanism of change explains how an intervention translates into a process that leads to an  
12 outcome, e.g. change in symptoms [11]. Thus, a mechanism is an explanatory concept that can  
13 be investigated by researching mediators, i.e., variables that explain changes statistically. Kazdin  
14 has formulated clear criteria on how to assess mediators of psychological treatments [12]:  
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- 21 ● Conduct sufficiently powered randomized clinical trials
- 22 ● Use valid and reliable measures for mediators that are sensitive to change
- 23 ● Apply a process design in which changes of the mediator temporally precede changes in  
24 therapeutic outcome and the mediator variable is measured repeatedly
- 25 ● Compare mediators that are theory-driven with non-specific mediators
- 26 ● Apply different dosages to prove that a stronger mediator-change leads to more  
27 therapeutic changes
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33 However, even after 13 years of Kazdin's suggestions on how to assess mechanisms of change  
34 in psychotherapy research [12], there are still an alarming lack of studies, inconclusive results  
35 (e.g. the treatment of depression in adults) [13] and very little research on change mechanisms  
36 for the treatment of adolescents [14, 15]. Cuijpers et al. conclude that despite more than 70 years  
37 of systematic psychotherapy research, we have no empirically validated mechanisms of change  
38 in adult psychotherapy [16]. The current systematic review will be the first to summarize the  
39 existing knowledge on mediators and theories of change in psychotherapy for adolescents.  
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45 To address these challenges related to mediators and measures of the mechanisms of change  
46 and therapies' efficacy in children and adolescents, besides other activities, the European  
47 Cooperation in Science and Technology (COST) funded a 4-year program named "European  
48 Network of Individualized Psychotherapy Treatment of Young People with Mental Disorders" with  
49 the acronym TREATme ([www.treat-me.eu](http://www.treat-me.eu)) that serves as a European multidisciplinary  
50 researcher network with researchers and clinicians from 30 countries. TREATme will review the  
51 academic research relating to mechanisms of change in patients aged between 10 and 30 years  
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3 receiving psychological treatments. For the current review, the part of the collected data set  
4 concerning adolescents only will be used. The aim is to provide an overview of existing research  
5 on psychological factors that mediate psychotherapeutic change in adolescents. We will conduct  
6 a narrative synthesis of all studies available up to 2020. The objectives of this review are the  
7 following:  
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- 10  
11 1. To identify which mediators and theories of change have been studied in psychotherapy  
12 with adolescents
- 13 2. To identify if there are adolescence-, disorder- or treatment-specific mediators
- 14 3. To critically evaluate the methodological approach of the current research data available  
15 on mediators in psychotherapy for adolescents  
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21 In order to obtain a comprehensive overview of the field of psychotherapy for adolescents, we will  
22 include various forms of psychotherapy and quantitative research designs. We will select all  
23 studies including a statistical test of mediation (e.g. Baron & Kenny or more advanced methods)  
24 [17] and will summarise study characteristics and results. We will discuss the extent to which  
25 these studies meet the most important requirements for mediator research that were mentioned  
26 earlier. Furthermore, we will relate mediators to the respective theories of change and describe  
27 which mediators successfully explain therapeutic change. Ultimately, this review can contribute  
28 to the challenging process of identifying underlying mechanisms of change in the process of  
29 psychotherapy for adolescents.  
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## 37 **Method**

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40 The review was registered in Prospero (CRD42020177535) and follows the preferred reporting  
41 items for systematic review and meta-analysis protocols (PRISMA-P) [18]. This article is based  
42 upon work from the COST (European Cooperation in Science and Technology) Action “European  
43 Network of Individualized Psychotherapy Treatment of Young People with Mental Disorders”  
44 (TREATme) aiming to improve knowledge and understanding of psychotherapeutic interventions  
45 in young people. The PICO model was used to define the research question.  
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## 51 **Eligibility criteria**

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3 Studies from any geographical location, written in English, available as full-text and published  
4 from inception onwards until February 23rd, 2020 that meet criteria, will be included in the review.  
5 Grey literature such as theses, dissertations or conference proceedings will also be included.  
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## 8 9 **Types of studies**

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11 Due to a lack of studies fulfilling all criteria for mediator research, we decided to include a broad  
12 range of study types. Studies will be selected if they include statistical analysis of mediators in  
13 psychotherapy. This comprises a) empirical quantitative studies following prospective,  
14 longitudinal, and case-control designs, b) terms related to or describing mediators, and c) a  
15 psychosocial intervention and/or psychotherapeutic intervention or treatment for primary/  
16 secondary prevention.  
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## 22 23 **Types of participants**

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25 The World Health Organization (WHO) defines adolescents as individuals between 10 and 19  
26 years of age [19], which was the age group selected for our inclusion criteria. These participants  
27 would have a mental disorder (e.g. depression, eating disorders) or psychological difficulties (e.g.  
28 binge drinking) and receive a psychotherapeutic intervention, including primary and secondary  
29 prevention programs. All comparators will be included as we will be investigating mediators in all  
30 treatments and not the efficacy of one treatment over another.  
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## 36 37 **Types of interventions**

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39 Studies will be included if they report an intervention aimed at preventing, ameliorating and/or  
40 treating psychological problems of adolescents by using psychosocial mechanisms and strategies  
41 in any setting (i.e., individual, family, group, inpatients, eMental health, etc.). These interventions  
42 should not be primarily biological or physiological. Examples of interventions include all branches  
43 or types of psychotherapy: psychodynamic, integrative, systemic, cognitive-based or cognitive-  
44 behavioural, interpersonal, humanistic (such as emotion-focused, supportive, motivational  
45 interviewing), psychoeducation and third-wave approaches (such as mindfulness-based  
46 therapies).  
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## 52 53 **Search strategy**

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3 The search strategy includes terms relating to or describing the intervention. These terms have  
4 been combined with the Cochrane MEDLINE filter for controlled trials of interventions and were  
5 adapted for PsycINFO [20]. Studies published from inception to 23.02.2020 have been sought.  
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7 The search string can be found in the online supplementary. The search was performed on the  
8  
9 23<sup>rd</sup> of February 2020.  
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## 11 **Data extraction**

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15 Study selection will be carried out by a group of 20 experienced researchers divided into ten pairs  
16 who will independently assess the eligibility of studies retrieved using the search strategy in two  
17 phases. The first phase comprises the screening of the titles and/or abstracts of studies that  
18 potentially meet the inclusion criteria outlined above. In the second phase, each pair of reviewers  
19 will evaluate the full text of these potentially eligible studies to see if they meet the inclusion  
20 criteria. Disagreements will be discussed by the pair, and a third reviewer will be involved if  
21 consensus cannot be reached. Finally, a fourth independent reviewer will perform an additional  
22 quality control check by assessing the eligibility of every fifth excluded study. Disagreements at  
23 this stage will be solved through discussion with the original review pair.  
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30 Data records will be managed with the support of Microsoft Excel [21]. A standardised form will  
31 be used to extract the information for the review. Extracted information will include: study setting;  
32 study population, participant demographics and baseline characteristics; details of the  
33 intervention and control conditions; study methodology; outcomes and times of measurement;  
34 assessed mediators; type of mediation analysis; and information for assessment of the risk of  
35 bias. Two review authors will extract information independently; discrepancies will be identified  
36 and resolved through discussion or with a third author when necessary.  
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## 43 **Critical appraisal**

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45 Although no standard form for evaluating mediation studies has been established, studies will be  
46 checked against general criteria for identifying mediators of psychosocial interventions in  
47 research, such as summarized by Kazdin and Lemmens et al. [12,13].  
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## 51 **Data synthesis**

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54 We will provide a narrative synthesis of the findings from the included studies, with a focus on the  
55 categories of mediators that have been tested, types of psychosocial interventions that have been  
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3 investigated, and mental disorders or psychological difficulties of adolescents that have been  
4 treated. It will be discussed if age-, disorder- or treatment-specific mediators can be identified.  
5 The age specific mediators will be identified by comparing results to mediators identified by  
6 reviews from adult psychotherapy.  
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## 10 **Outcomes and prioritization**

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13 The primary outcome will be mediators related to change in mental health problems or disorders  
14 in adolescents measured by a validated instrument or tool made for that purpose. Data on the  
15 disorder will be categorised into depression, anxiety, substance misuse, externalising problems,  
16 severe mental illness (e.g. psychosis, bipolar disorder) and others (e.g. eating disorders). The  
17 therapies will be categorised into: psychodynamic, integrative, systematic, cognitive-based or  
18 cognitive-behavioural, interpersonal, humanistic, psychoeducation, and third-wave. Mediators  
19 and instruments for assessing them will be identified. The statistical analyses for evaluating the  
20 effect of mediators will be recorded. Pre-treatment and post-treatment scores will be noted, and  
21 the differences compared.  
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## 29 **Risk of bias in individual studies**

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31 The Mixed Methods Appraisal Tool will be used to evaluate the overall study quality using a formal  
32 risk of bias assessment [22]. This tool permits the appraisal of the methodological quality of five  
33 categories of studies: qualitative research, randomized controlled trials, non-randomized studies,  
34 quantitative descriptive studies, and mixed methods studies.  
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## 39 **Patient and Public Involvement**

40 No patient was involved in planning and conducting the study.  
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## 44 **Ethics and Dissemination**

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46 No ethical approval will be necessary to conduct the review as no additional empirical data will be  
47 assessed. Results from the review will be disseminated through a publication in a peer-reviewed  
48 open access journal and through scientific communication using the COST-action homepage.  
49 The data set that will be established during the search and extractions will be published in an  
50 open data repository after the acceptance of the publication of the review order to facilitate access  
51 to students, academia and professionals. Additionally, results will be disseminated in  
52 conferences, seminars, congresses or symposia.  
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## Discussion

As far as the authors are aware, this is the first systematic review of its kind, assessing mediators of psychotherapeutic changes in adolescents. The findings will inform how much is currently known about such mediators and the practical implications of this knowledge for treatment planning and outcomes. The results will also shed light on how these empirically studied mediators correspond with the theoretically putative mechanisms of change in particular models of intervention. Using qualitative synthesis, we will evaluate and comment on the conclusiveness of age-, disorder-, or treatment-specific-mediators and map out the most pressing needs for future research on mediators and mechanisms of change in adolescent psychotherapy. The review will provide a basis for comparing our results with those of systematic reviews in adults, to assess whether there are similar or different mediators in adolescents that explain therapeutic change.

The strengths of this protocol include the gathering of a large multidisciplinary group of international researchers with long-standing accumulated experience in the area that have worked on this topic for three years through regular online and face to face meetings. Furthermore, the group has consulted international experts in the field to develop the protocol. A structured quality assurance will be carried out, as well as several search updates to ensure the completeness of the data set. The whole data set will be offered to other research groups following the recommendations of the open science initiative.

Limitations of this protocol include the use of broad inclusion criteria to describe the existing knowledge comprehensively and increase external validity, which likely limits the possibility of causal conclusions by also including non-randomised controlled trials. For the same reason, it is likely not feasible to estimate aggregated effect sizes for the identified mediators. Our conclusions on mechanisms of change will only be related to empirical quantitative studies as we have excluded qualitative and theoretical studies. As there is no generally accepted gold standard for mediation analysis, we expect much variance in the studies, which could lead to our results being inconclusive or inconsistent. Also, we are analyzing both subclinical conditions and diagnosable disorders, as well as intervention and prevention studies, which may lead to less consistent or coherent results. We have chosen to do this in order to address the adolescent age group holistically and aim to report the results separately in order to establish independent conclusions. As the rater team consists of a fairly large group, inter-rater bias has to be strictly monitored, and so a fourth independent reviewer will be introduced to perform additional quality control checks.



## a. Contributorship statement

All co-authors provided a substantial contribution to the conception and design of the work by developing the research question, the search string and carrying out the stage 1 screening (ST, AS, EH, SP, JV, AA, RB, SCC, DG, YI, JM, PMP, FMV, CPM, MR, MSH, JIR, SJS, TSP, RU, CMDS). The current manuscript was drafted by the first and second as well as the last author (ST, AS, CMDS) and was corrected and finally approved by the other authors (EH, SP, JV, AA, RB, SCC, DG, YI, JM, PMP, FMV, CPM, MR, MSH, JIR, SJS, TSP, RU). RU coordinates the overall COST initiative. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

## b. Competing interests

There are no competing interests.

## c. Funding

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## d. Data sharing statement

At the moment, the data-set is available from the first author upon reasonable request.

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 43 "juvenil\*" OR "young\*" OR "subadult" OR "immature" OR "adolescen\*" OR "puberty" OR "pubertal" OR  
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 52 psychoeducation OR "group therap\*" OR "family therap\*" OR "general psychiatric management" OR  
 53 GPM OR MA "Mind-Body Therapies" OR "supportive psychotherapy" OR DE "Psychotherapy" OR DE  
 54 "Counseling" OR DE "Psychoeducation" OR DE "Psychosocial Readjustment" OR DE "Psychotherapeutic"  
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13 treatment" OR "Acceptance and Commitment Therapy" OR "ACT" OR "dialectical behavior therapy" OR  
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