
Generating outcome domains for COS development: Method for a large and international patient and public participation. The PROCEED Study

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Depression

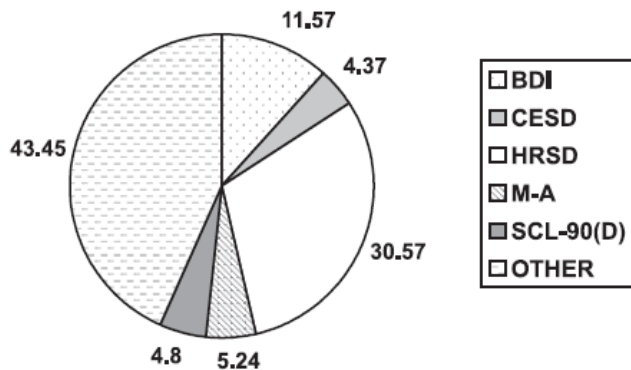
- **A frequent and disabling disorder:**
 - Prevalence: around 6% *(Kessler 2013)*
 - Lifetime prevalence: 15-18% *(Bromet 2011)*
 - One of ten patients in primary care *(Malhi 2018)*
 - Fifth leading cause of Years Lived with Disabilities *(Vos, 2017)*
 - 4.2% (3.2,5.3) of the Global Burden of Diseases. *(Vos, 2017)*
- **Treatment options:**
 - Medication
 - Psychotherapy
 - neurostimulation

Outcomes in trials

- Multiple outcomes *(Tyler 2011)*
- Heterogeneity *(Tyler 2011)*
 - 280 tools published *(Santor 2006)*

Outcome	Frequency reported
Hamilton Depression Rating Scale	11
Clinical Global Impression	4
DSM-IV diagnosis of depression	4
Montgomery-Asberg Depression Rating Scale	4
Beck Depression Inventory	3
Children's Depression Rating Scale	3
Hospital Anxiety and Depression Score	3
Quick Inventory of Depressive Symptoms	2

Basic Science Studies



Treatment Outcome Studies

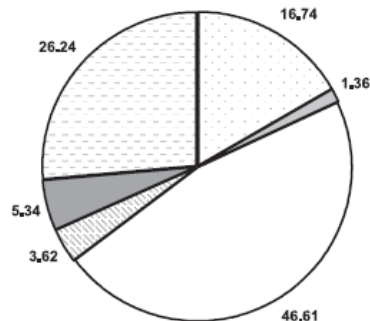
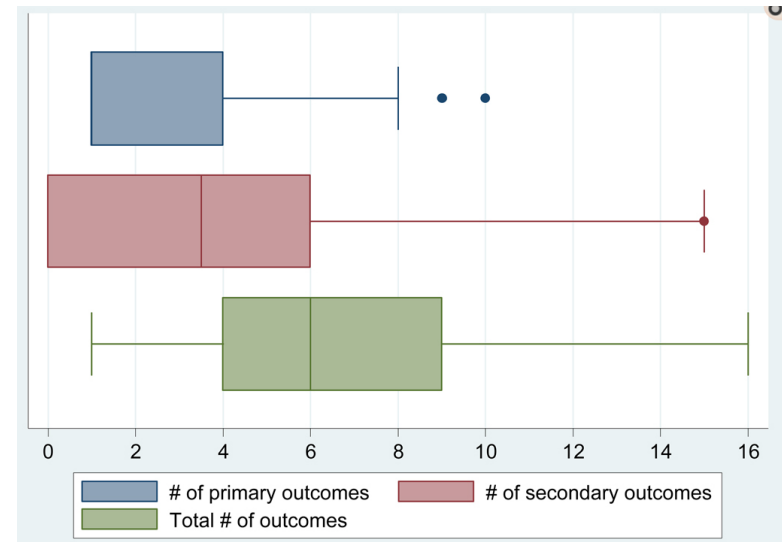
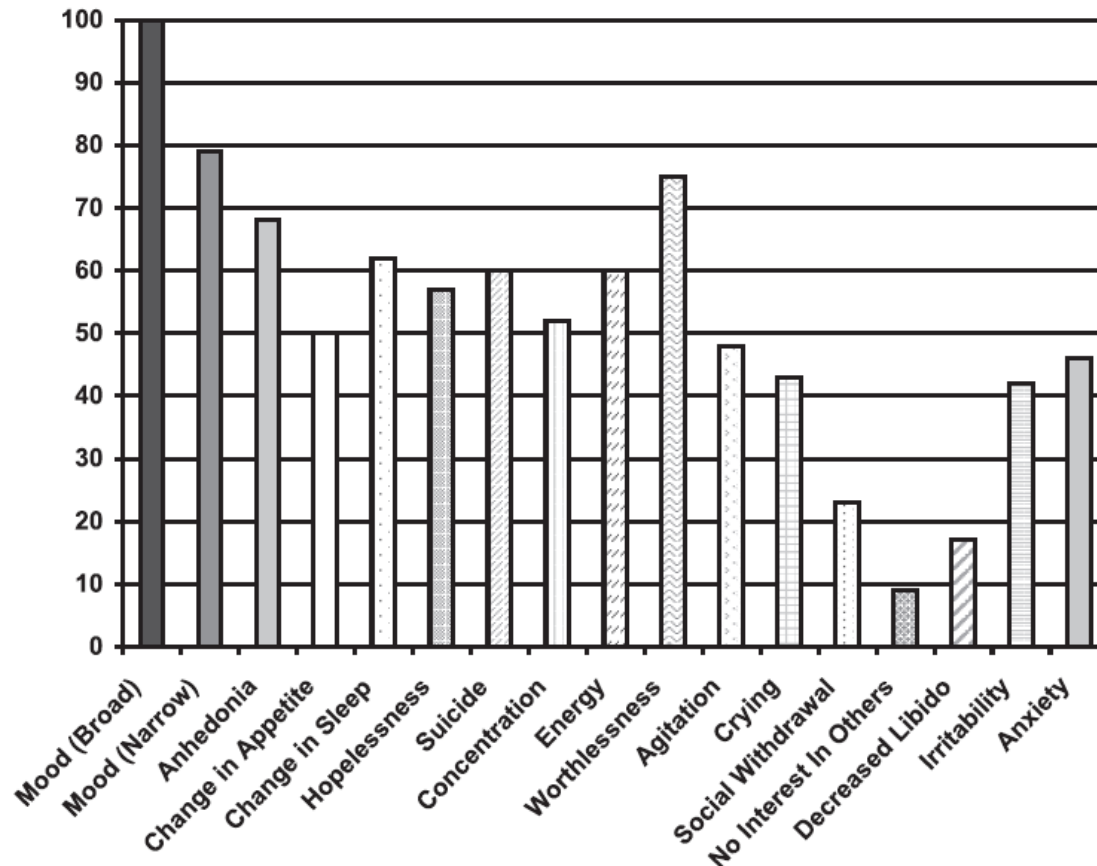


FIGURE 3 Pie graphs showing the proportionate frequency of use of measures of depression. In total some 70 different measures of depression were used in the past 10 years. However, only 6 measures were used with any frequency.



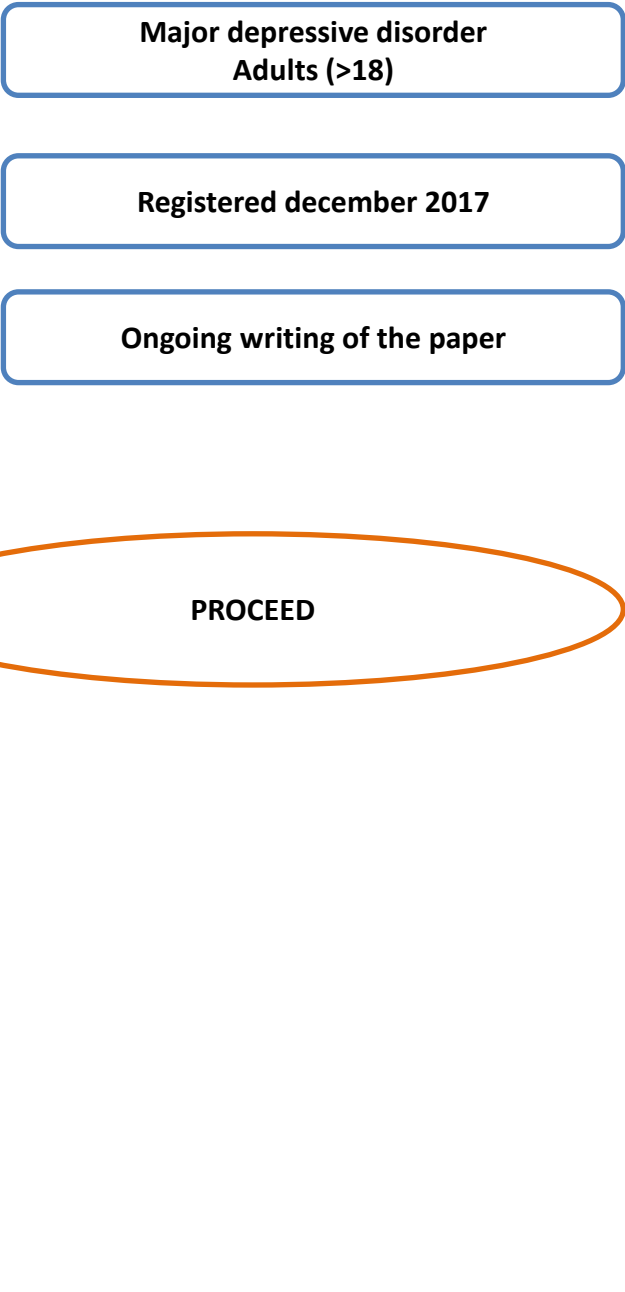
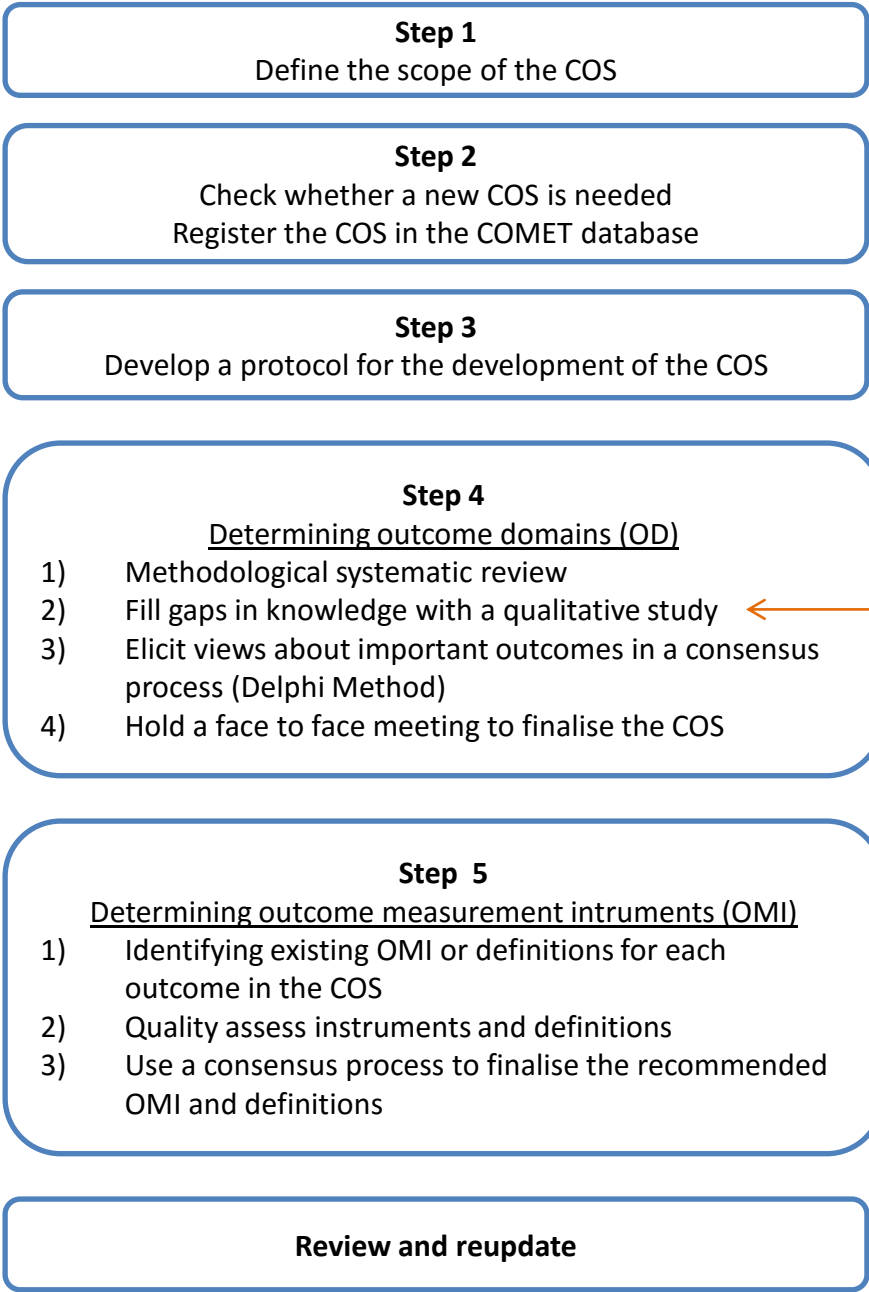
What is measured?

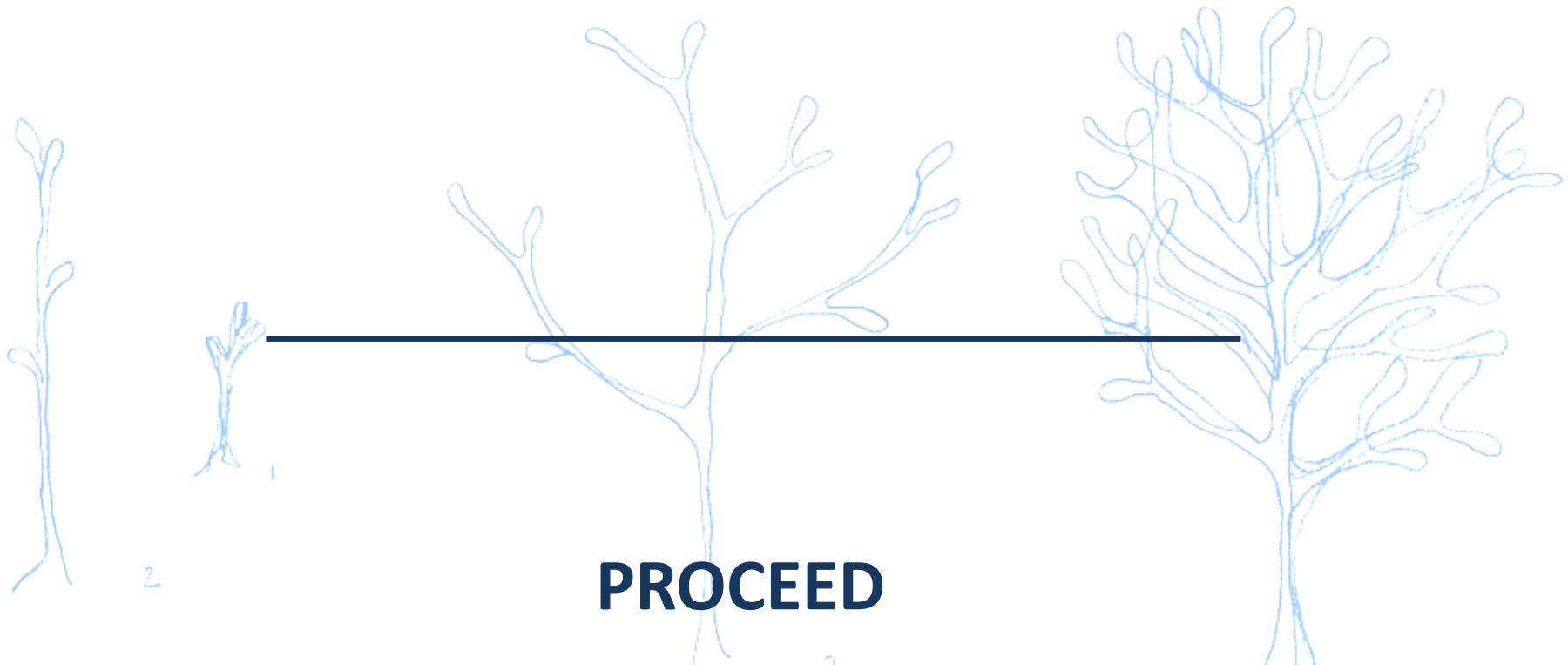
Heterogeneity in assesement of domains: 20% of studies did not operationalized mood with « sadness » or « depressed ».



Percentage of scales assessing symptom domains

(Santor 2006)





PROCEED

Participative Research on Outcomes' and Core Expectations' Elicitation for Depression

<http://clinicalepidemio.fr/depression/en/>



- **Objective:**

Identifying the diversity of expectations for the treatment of depression.

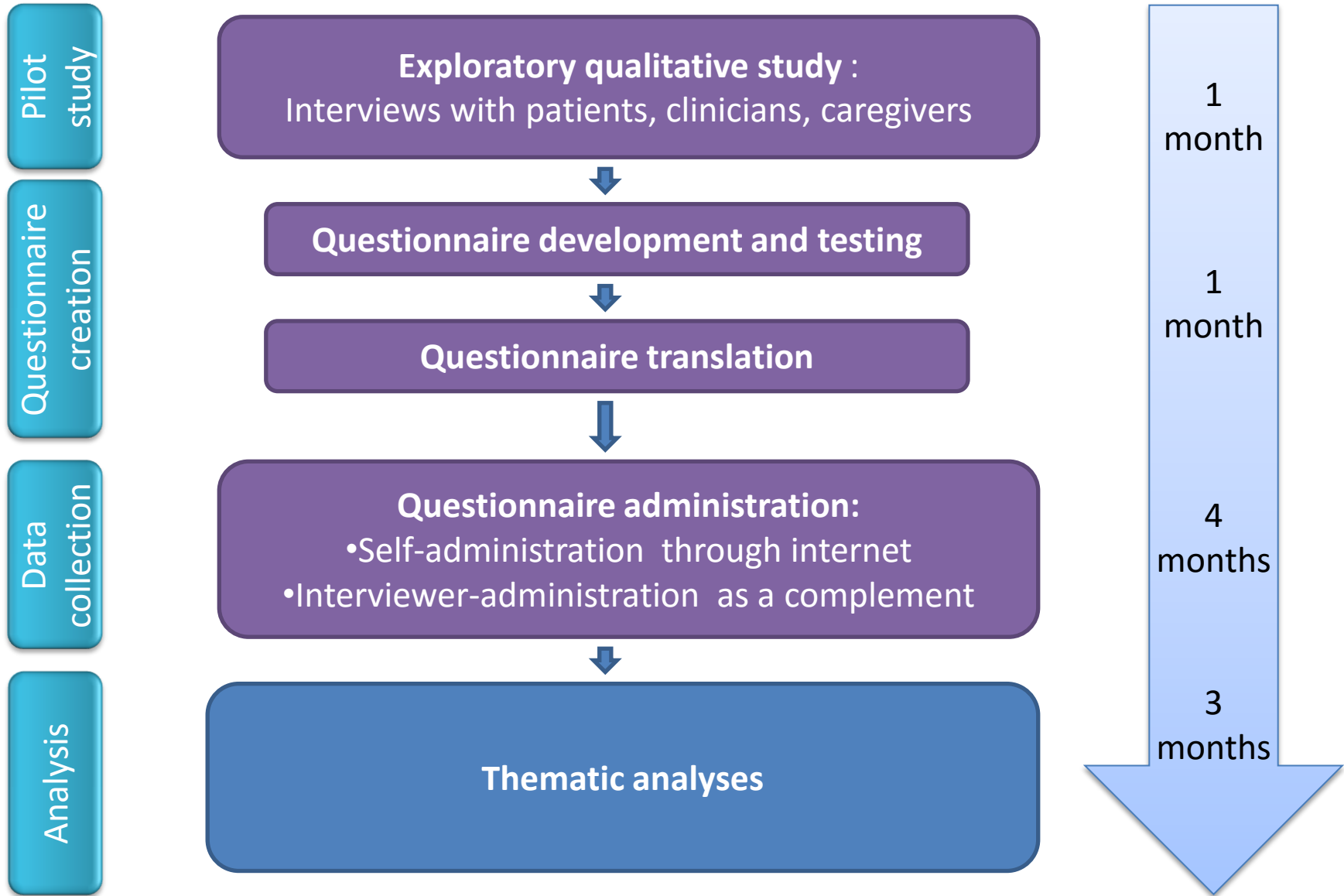
- **Method:**

- Online international survey based on a few open-ended questions
- Population:

<u>Patients</u>	<u>Carers</u>	<u>Clinicians</u>
<ul style="list-style-type: none">➤ Over 18 years old➤ Report ongoing or previous episode of depression	<ul style="list-style-type: none">➤ Over 18 years➤ Report supporting a patient during an episode of depression	<ul style="list-style-type: none">➤ A professional that deals with MDD during its occupation



METHOD





Exploratory qualitative study



- Objective:

Determining open-ended questions for the online questionnaire that would bring back **accurate and rich responses**.

- Purposive sampling:

- 9 Clinicians :profession, experience, workplace
- 4 Carers: link to the patient
- 6 Patients: age, gender, ongoing/previous depression, severity.



Open-ended questions for patients



- For all patients:
 - **For you, what is the most difficult aspect of depression to live with or endure?**
 - **For you personally, what might improve or refine treatments for depression?**
- For patients who consult/have consulted a healthcare practitioner:
 - **What prompted you to seek out a healthcare professional?**
- For patients who declared being no more suffering under depression :
 - **What made you consider yourself as no longer depressed?**



Open-ended questions for carers



- **What do you consider to be the most difficult aspects to live with for your family member/friend with depression?**
- **What do you consider most important to address in a depressed person?**
- **What types of improvement do you expect from the treatment of depression for your family member/friend?**



Open-ended questions for clinicians



- According to your experience, what do you consider to be the most difficult aspects to live with for your patients with depression ?
- According to you, what aspects of their condition should be prioritized for depressed patients ?
- Under which criteria do you consider a patient to be cured of his/her depression?
- In the case of rheumatoid arthritis, studies have for a long time used the number of painful and swollen joints to evaluate treatment efficacy. However it has been shown that patients expect a reduction in their level of fatigue. Ever since, fatigue has been measured in efficacy studies. According to you, which criteria would be essential to measure in treatment efficacy studies for depression?



Caring for depression: what matters to you?

Help us to improve research on the treatments of depression !

We invite you to participate in [PROCEED](#), an **international scientific survey** with the goal to identify your **expectations for treatments of depression**.

You are **eligible** if :

- you are over 18 years old **AND**
- **you suffered or you are currently suffering from an episode of depression OR**
- you are an **informal caregiver**, that is to say a family member or a friend of someone who has suffered or is suffering from depression **OR**
- you are a **healthcare practitioner** working with of depressed patients (for instance : psychiatrist, psychologist, nurse, general practitioner/family doctor, etc)

PROCEED is a **participative** research project involving patients at each step of the research process: **please answer the anonymous questionnaire** and **share it** with others.

The more participants will be included, the more we will be able to make things change in the **improvement of treatment for depression**..

To make your voice count, we invite you to answer ONCE the APPROPRIATE questionnaire below. It will take less than 10 minutes

Your participation in the study is voluntary. Participation will not impact your medical care. You can choose to cease your participation at any moment, without justification. At the end of the questionnaire you will have the possibility to give your e-mail address if you want to be aware of the results of the study AND/OR to be recontacted in order to participate to the following steps of the study. Your e-mail will be stocked in one database unlinked with the database with your responses to the questionnaire in order to preserve its anonymity. Data are anonymous and stored on a non shared secure server of a private host. IP address is not tracked. Data will be used only by researchers of the team to answer the questions of the PROCEED study. The results of the study will be published in a scientific journal and communicated via scientific conferences. Astrid Chevance is the Principal Investigator of the study. She is a PhD student in Public Health at the Paris-Descartes University working in the METHODS team of the Center for research in epidemiology and statistics. The protocol of the study has approved by the the CEEI/IRB (IRB00003888) on the 15th of May 2018 (Paris, France). We declared the study to the French Data Protection Authority (CNIL).

Please complete only one questionnaire.

[Download the participant note](#)

Patient

I accept to participate as a patient

[Start](#)

Family or friend

I accept to participate as family or friend of a depressed person

[Start](#)

Healthcare professional

I accept to participate as a healthcare professional

[Start](#)

3183 participants have shared their expectations with us. Would you like to share yours?

Thank you !

<http://clinicaledpidemio.fr/depression/en/>



Recruitment



<u>Patient</u>	<u>Carers</u>	<u>Clinician</u>
<ul style="list-style-type: none">➤ Over 18 years old➤ Report ongoing or previous episode of depression	<ul style="list-style-type: none">➤ Over 18 years➤ Report supporting a patient during an episode of depression	<ul style="list-style-type: none">➤ A professional that deals with MDD during its occupation

Online recruitment:

- Articles in general and specialized media websites
- Advert on websites of patient or professional associations
- E-mail to professionals
- Share and advert on social networks

Thematic Analyses

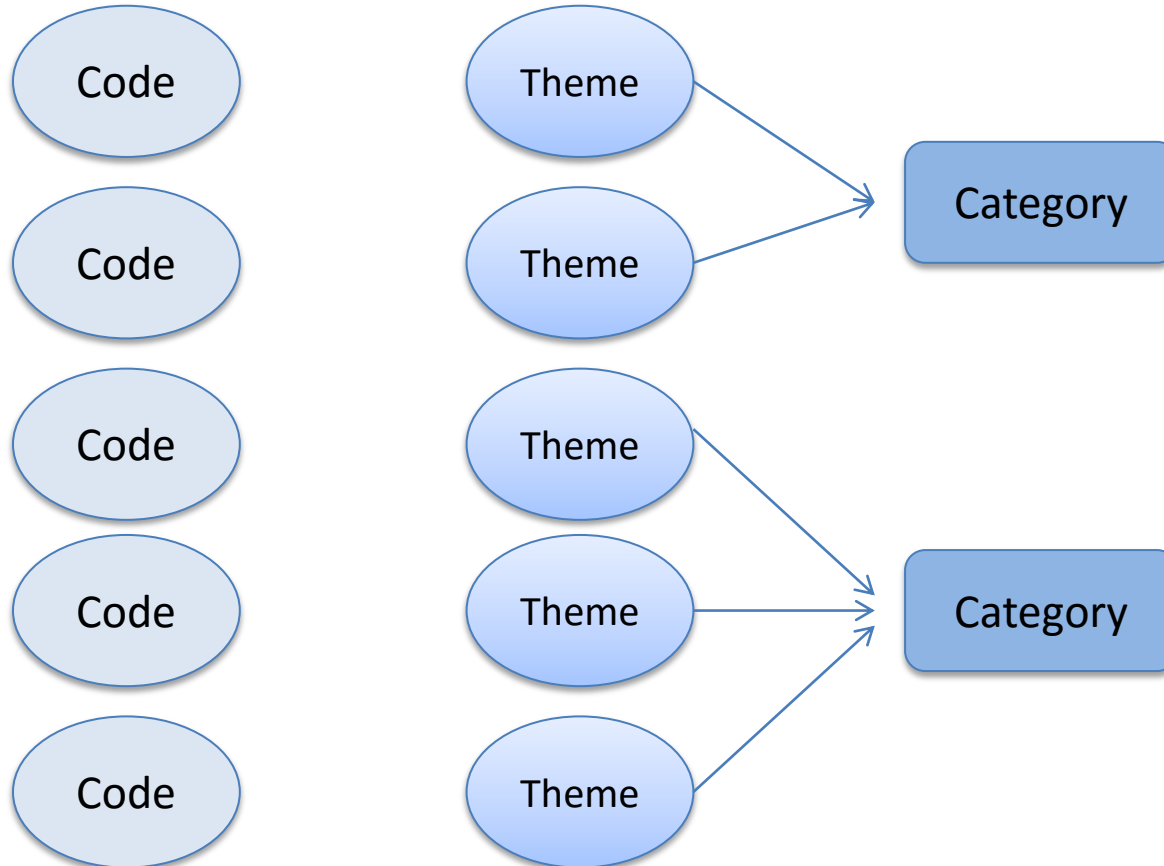
Collaborative decision

Exploratory code

Coding themes

Mapping themes

Validation



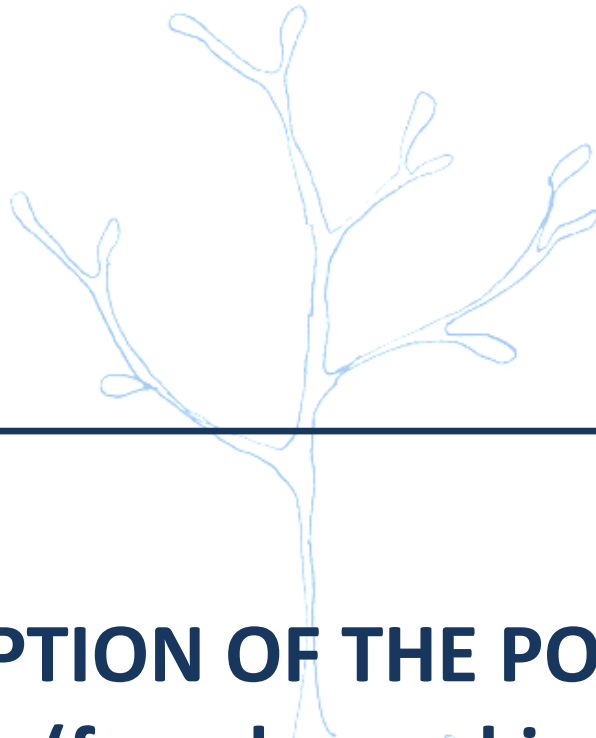
Map of the expectations of patients, clinicians, and caregivers

Two independent investigators (at least one out of the lab)

Investigators and participants



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4

**DESCRIPTION OF THE POPULATION
(french speaking)**



Patients (n =1479)

- Socio-demographical-characteristics:
 - **Women:** 74%
 - **Age:** 23 % <30 years , 25%[30-49], 3%>50
 - **Residency:** 25 countries (88% France)
- Experience of depression :
 - **Currently depressed:** 55%
 - **Severity** (PHQ-9): 15% without depression, 17% light, 21% mild, 23% mildly severe, 22% severe.
 - **History of suicidal attempt:** 32.5%
- Treatment:
 - 66% consulted a **psychiatrist**
 - 5.3% consulted only their **GP**
 - 70% are/have been once under **antidepressant medication**
 - 57% are/have been one under **psychotherapy**

Carers (n=402)

- Socio-demographical characteristics:
 - **Women:** 70%
 - **Mean age:** 46 (18)
 - **Residency:** 17 countries (80% France)
 - **Income:** 74% declared having sufficient income
 - **Employment status:** 49% employed, 22% retired
- Experience of depression:
 - **Personal history of depression:** 52%
 - **Lived with the depressed person:** 40%
 - **Relationship with the depressed person:** 15% were taking care of their husband, 12% of their mother, 11% of a friend.

Clinicians (n=392)

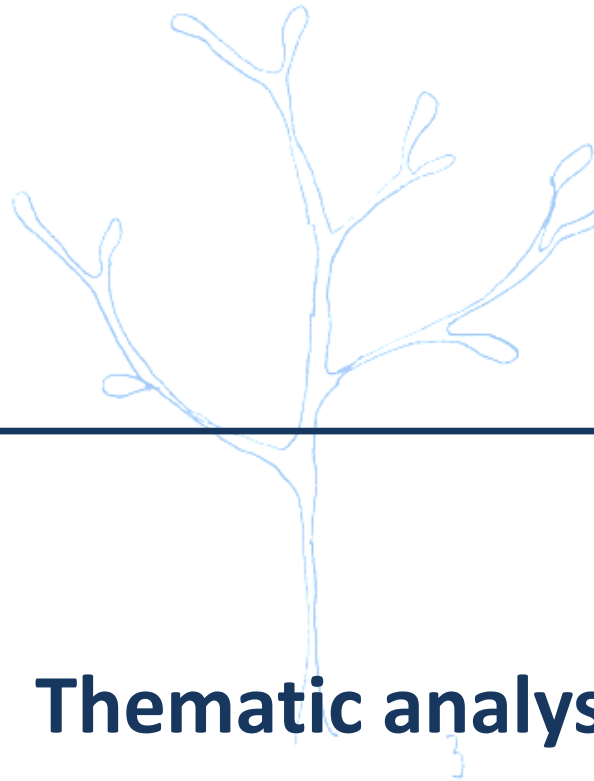
- Socio-demographical characteristics:
 - **Women:** 54%
 - **Mean age:** 38.7 (12.4)
 - **Practice:** 16 countries (89% France)
 - **Profession:** 57% psychiatrist, 13% psychologist, 8% nurses, 6% GP
- Experience of depression:
 - **Personal history of depression:** 26%
 - **Relative with an history of depression:** 56%



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Thematic analysis

Theme analysis of the french data

- **Coders:**
 - 2 psychiatrists, master degree in social science
 - Background : Psychoanalysis and Marketing, CBT and Sociology
 - Mother language
- **Coding :**
 - Order of coding: clinicians, carers, patients
 - Codebook made of verbatims
 - Double coding for 300 individuals of each group (900 individuals and 3100 responses).
 - Measurement of data saturation (*Tran et al. 2017*)
 - Single coding (1100 patients, 100 clinicians) with a random control on 10%
 - Consensus on 95.6%of the code

Example of themes

Irritability

Help for choosing between psychotherapies

Mental pain

Anger

Self-esteem

Attention trouble

Memory loss

Loss of emotion

Tailored medication dose

24/24, 7/7 available care

Lack of energy

Quality of sleep

Loneliness

Verbatims: the example of Mental Pain

- **Patients:**

- *Moral suffering made my daily life unbearable. I had to endure physical pain in my life but I consider them insignificant in comparison to depression.*
- *The worst is the unexplainable pain that I'm feeling. I'm suffering so much that I can't speak anymore.*
- *I am suffering psychologically. It is so unbearable that it leads you to wish that everything could stop. You start to think that death could be less painful.*
- *When depression is severe, mental pain turns into physical pain*
- *The worst is how my children look at me when I am overwhelmed by suffering.*
- *Depression is a psychological torture.*
- *An extreme pain that is really difficult to understand by our relatives (it can't hurt because it is NOT physical)*
- *No-one can imagine what depressed people are experiencing deep inside: the pain and others lack of belief about the pain.*

- **Carers:**

- *Psychological distress*
- *Mental pain*
- *The psychological suffering is a torture for him*
- *Inside suffering*
- *Suffering of her own thoughts without being able to share it*

- **Clinicians:**

- *Mental pain*
- *Inside pain*
- *Inside suffering*
- *Psychological pain*

Discussion

- **Recruitment:**
 - **Fast:** 4 months
 - **Low cost:** home made website
 - **High number of participants:** 2273 french speaking, 522 other language
 - **Diversity of participants:**
 - **International** (3 languages, around 30 countries from 4 continents)
 - All pre-specified categories beside elderly patients (>65).
- **Quality of the data :**
 - Rich responses
 - Accurate
 - Comprehensive

Further analysis

- Analysing the data in english and german
- Merging the themes in one language
- Mapping the themes in categories

10.20.2018	Patients	Healthcare professionals	Informal caregivers
English-speaking	175	51	15
German-speaking	116	152	13

A COS for DEPRESSION

Who we are:

International scientific advisory board :



Pr Andrea CIPRIANI

NIHR Research Professor at the Department of Psychiatry, University of Oxford and Honorary Consultant Psychiatrist at the NHS Foundation Trust in Oxford (Great Britain)



Pr Pim Cuijpers

Professor of Public Health and Headchief of the Department for Evidence based Medicine and clinical Epidemiology at the Donau-University of Krems (Austria). He is also joint director of the Research Triangle Institute International at the University of North Carolina Evidence-based Practice Center (USA).



Eiko FRIED

Assistant Professor at Leiden University working on the measurement and modeling of mental illness



Pr Gerhard GARTLEHNER

Professeur de Santé Publique, directeur du département d'épidémiologie clinique et de médecine fondée sur les preuves à la Donau-Universität de Krems, en Autriche. Il est aussi directeur adjoint de l'institut international de recherche Triangle du Centre de médecine fondée sur les preuves de l'université de Caroline du Nord (USA)



Dr Evan MAYO-WILSON

Assistant Scientist at the Epidemiology department of the Bloomberg Scholl of Public Health at the Johns Hopkins University of Baltimore (USA).

Mrs Suzanne T., patient representative

Pilot team :



Astrid Chevance

PhD student, principal investigator. METHODS team.



Dr. Viet-Thi Tran

Researcher, supervisor of the PhD. METHODS team.



Pr. Philippe Ravaud

Director of the CRESS and the METHODS team, supervisor of the PhD.

<http://clinicalepidemio.fr/depression/en/>