

# BMJ Open Psychotropic medication and psychotherapeutic treatment of adults with intellectual disabilities (PROMPT-ID): a cross-sectional, epidemiological study in Saxony, Germany

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**To cite:** Koch A, Dobrindt J, Schützwohl M. Psychotropic medication and psychotherapeutic treatment of adults with intellectual disabilities (PROMPT-ID): a cross-sectional, epidemiological study in Saxony, Germany. *BMJ Open* 2018;**8**:e025947. doi:10.1136/bmjopen-2018-025947

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2018-025947>).

Received 17 August 2018  
Revised 12 September 2018  
Accepted 19 September 2018



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## ABSTRACT

**Introduction** The psychotropic medication and psychotherapeutic treatment of adults with intellectual disabilities study is a cross-sectional, epidemiological study carried out in Saxony, Germany. The main aim of the study is, among others, to assess the prevalence and quality of psychotropic medication in adults with ID.

**Methods** Inclusion criteria are mild to profound forms of ID and an age of 18 years or older. A representative sample is realised by a two-stage sampling procedure. Study participants will be recruited from sheltered workshops (SW) and sheltered housings (SH). The stratified cluster sampling is realised by a random selection of service providing institutions followed by a random selection of adults with ID. An estimated total number of n=200 study participants via SW and n=400 via SH will be contacted to obtain data of approximately n=131 study participants recruited through SW and n=232 participants through SH. Thus, based on a psychotropic medication prevalence of 30%, an estimated number of n=109 in-depth interviews about psychotropic prescription practice will be carried out. Data collection is realised through interviews with key carers in the living environment. If psychotropics are prescribed currently, basic information (eg, dosage, treatment duration) are obtained, and a newly developed interview targeting the quality of the psychotropic medication treatment is conducted both with the carers and with the prescribing physicians. In addition to the prevalence and quality of psychotropic treatment, other parameters (eg, mental healthcare utilisation, psychiatric symptomatology, problem behaviour, institutional factors and parameters of the provision area) are assessed using well-established instruments.

**Ethics and dissemination** Approval of the responsible ethics committee was obtained. Findings will be disseminated to participating institutions, published in journals and conferences and fill the lack of representative data that is urgently needed in this often criticised health service area. They shall help to improve mental health services in adults with ID prospectively.

**Trial registration number** NCT03558815; Pre-results.

## INTRODUCTION

In approximately 1%–2% of the general population an intellectual disability (ID) occurs.<sup>1</sup> The reported prevalence rates of mental health problems in people with ID vary substantially. This results from a

## Strengths and limitations of this study

- Strengths comprise the realisation of a representative study sample by using a cluster sample stratified by type of service provider and workshop size/type of accommodation and the subsequent realisation of a two-stage random sampling procedure.
- However, a small number of adults with intellectual disability (ID) not using at least one of the facilities of service providers either in the working or the living environment will not be included into the study.
- A further strength of the study is that both the basic measures about psychotropic medication and the newly developed interview about the psychotropic prescription quality were developed in collaboration with three clinical experts.
- In addition, all measures were pilot tested and all interviewers were trained in all relevant measures.
- The sample includes individuals with severe and profound levels of ID, for which reason no personal interview with the adults with ID was conducted.

heterogeneity of methodological approaches and varies depending on the sampling procedure, on the diagnostic classification system used and the inclusion or exclusion of problem behaviour. One of the most elaborate studies, including adults with mild to profound forms of ID, reports prevalence rates of mental-ill health between 15.6% and 40.9% depending on the diagnostic criteria used (based on Diagnostic and Statistical Manual of Mental Disorders Fourth Edition – Text Revision criteria or clinical diagnoses) and the inclusion or exclusion of problem behaviour.<sup>2</sup> A representative German study of adults with mild to moderate ID reports a point prevalence of any mental disorder of 10.8% (based on the 10th revision of the International Statistical Classification of Diseases and Related Health Problems criteria) and of 45.3% of at least one moderate problem behaviour.<sup>3</sup>

Some people with ID require psychiatric and/or psychotherapeutic and/or

psychosocial treatment. Worldwide, the prevalence of psychotropic medication (PM) treatment is high in this vulnerable population. Prevalence rates of PM varies between 35% and 58% in western English-speaking countries.<sup>4-7</sup> The most recent study from Germany reports a 19.5% point prevalence rate of PM (excluding anticonvulsants) in adults with mild to moderate ID employed in sheltered workshops.<sup>3</sup> Another German study conducted in 16 sheltered housing institutions in Berlin reports a PM prevalence of 34.4% on average, with a wide range of 7% and 62.3% between housing institutions.<sup>8</sup>

A number of studies assessed the prescription practice of PM in adults with ID. Findings showed that PM is often prescribed without sufficient diagnostics or insufficient or missing indication, too often as long-term medication, too often as pro re nata (PRN) medication, without regular monitoring of effects, side effects and medication parameters; non-medication alternatives are rarely explored and polypharmacy is common.<sup>9-14</sup> Ethical issues of a good clinical prescription practice of PM in people with ID are discussed and guidelines for the psychotropic treatment of problem behaviour in people with ID are established.<sup>15-19</sup>

Regarding psychotherapeutic interventions, there is a lack of studies targeting the prevalence of psychotherapeutic interventions for people with ID and a poverty of good quality randomised controlled trials assessing the efficacy or the effectiveness of psychotherapy in adults with ID.<sup>20</sup> Reviews show moderate effects of specific psychotherapy modules in people with ID.<sup>21-23</sup>

Yet, a lack of psychotherapeutic services to meet the mental health needs of people with ID is reported.<sup>24-26</sup> Possible barriers for adequate psychotherapeutic mental health service provision might be the ID-specific modification of techniques and therapeutic setting, which includes (among others) the use of Easy Read language, more time and repetitions, shorter therapy sessions and the support and involvement of the caring environment.<sup>24-29</sup> Furthermore, a subjectively limited competence of psychotherapists, problems in understanding and a lack of temporally resources and accessibility of facilities is reported.<sup>26</sup>

However, there is a lack of methodologically sound studies targeting the mental health service provision in adults with ID. Studies that investigate the prescription practice of PM against current guidelines and that identify the prevalence of psychotherapeutic treatment in this population are urgently needed.

Thus, the psychotropic medication and psychotherapeutic treatment of adults with intellectual disabilities (PROMPT-ID) study pursues four aims:

1. To assess the prevalence of PM and psychotherapeutic treatment in adults with mild to profound ID.
2. To assess quality of PM in adults with mild to profound ID.
3. To identify predictors of PM and barriers into psychotherapeutic treatment in adults with mild to profound ID.
4. To identify predictors of good clinical practice in PM treatment of adults with mild to profound ID.



## METHODS AND DESIGN

The PROMPT-ID study is a cross-sectional epidemiological study funded by the German Research Foundation. It will be carried out between May 2017 and October 2019. The study is conducted by the Mental Health Services Research Group at the Department of Psychiatry and Psychotherapy, Technische Universität Dresden. The study area covers rural and urban areas in the Free State of Saxony, Germany. Data collection is realised between October 2017 and April 2019.

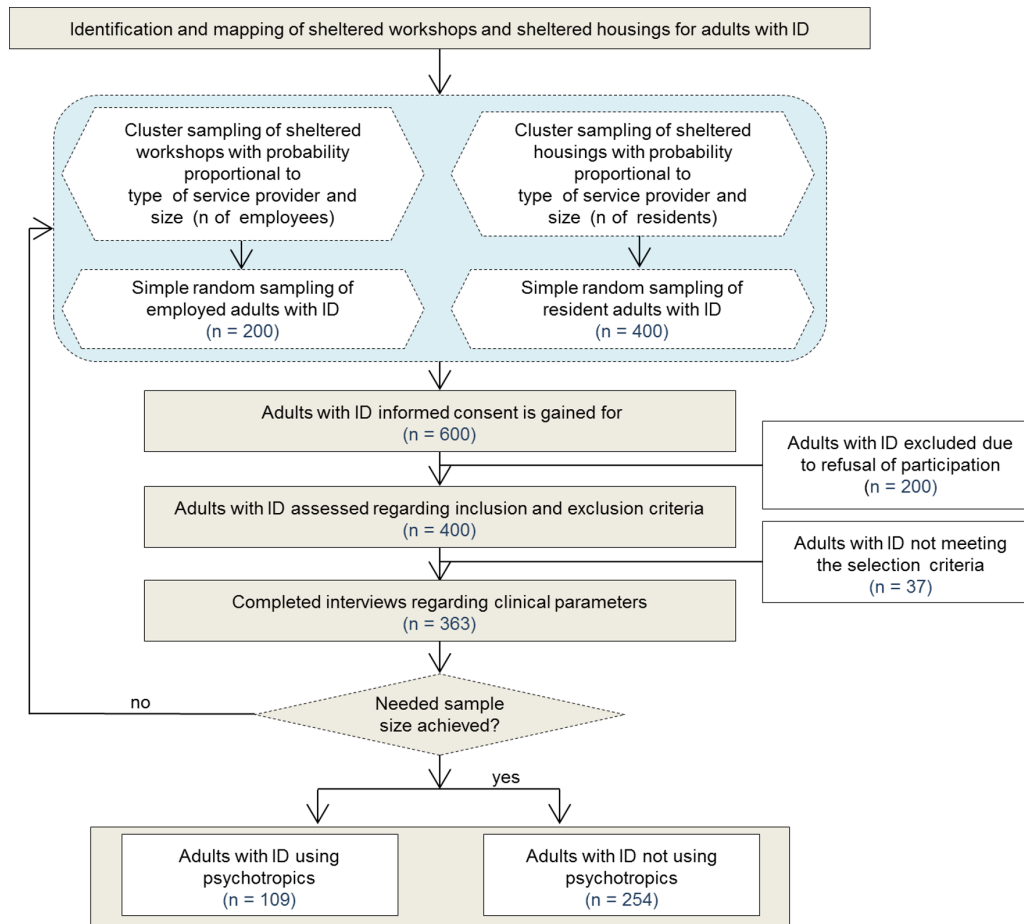
## Participants

### Inclusion and exclusion criteria

Inclusion criteria are defined as adults with mild to profound levels of ID with an age from 18 years onwards. Adults with a learning disability are excluded. Severity of ID is determined by the established diagnosis to be found in the records, the assessment based on the definition of ID by the American Association of Intellectual and Developmental Disabilities and on well-defined criteria of adaptive behaviour impairment in different degrees of ID. The ID assessment asks for causes and age at the onset of cognitive impairment as well as the availability of an established diagnosis of ID. Furthermore, the key carer or relative is asked to ascribe the person with ID to a global rating of the highest level of conceptual, practical and social functioning that the person has ever been capable of. The levels of functioning are assigned to different levels of disability (1=learning disability, 2=mild ID, 3=moderate ID, 4=severe ID and 5=profound ID)\*. Participants meet the first inclusion criterion if an established diagnosis of ID is recorded. If there is no established diagnosis available, the first inclusion criterion is met, if the cause and the age of ID onset fulfil the ID criteria and if their skills are rated on every level of ID except for a learning disability.

## Sampling

There are no regional registers of adults with ID in Germany. Thus, this population will be accessed through service providers, which are divided into services for accommodation, subsequently referred to as sheltered housings (SH), and services for employment, subsequently referred to as sheltered workshops (SW). Adults with mild or moderate ID are most likely employed in SW. In addition, adults with ID living with relatives or alone are accessible via SW. Adults with severe or profound ID or with dual diagnoses or additional severe problem behaviours are likely to use services for accommodation including day-structuring services. In order to reach people with different severity degrees of ID and of different living conditions, we decided to recruit both from SW and from SH for people with ID (figure 1).



**Figure 1** Sampling procedure.

### Recruitment of sheltered workshops and sheltered housings

In order to identify all SW for people with ID in Saxony, a systematic and comprehensive search was conducted. The starting point was a list of SW provided by a consortium of SW representatives ('Landesarbeitsgemeinschaft Werkstätten für behinderte Menschen Sachsen e.V'; LAG WfbM Sachsen). This list comprised a total of 119 SW for adults with ID in Saxony. In addition, we searched the internet for further corresponding operating sites based on the workshops listed by the LAG WfbM Sachsen. Every operating site with a different address was counted separately. Thus, a total of 158 SW for people with ID were identified. SW were contacted and asked for information about the total number of employees and the amount of employed adults with ID. The 74 cooperating SW were stratified by size and by type of the service-providing organisation. To obtain sufficiently large clusters to realise a random sampling of institutions and due to the common German structure in social service providers, the different types of service providers were allocated to the dichotomous division in secular versus ecclesial type of service provider.

The systematic search for SH is analogous to the SW search described above. The initial source was a list provided by the league of free social welfare in Saxony ('Liga der freien Wohlfahrtspflege in Sachsen') that

represents the six umbrella organisations of social welfare in Saxony. A comprehensive internet search and any additional information provided by the SH generated a total number of 311 services for SH for adults with ID (facilities with different addresses were counted separately). After contacting all main residences and requesting for information about the capacity and amount of residents with ID per institution, we stratified the 196 cooperating SH by type of accommodation (residential home, external residential group, outpatient assisted living) and by the type of service-providing organisation (secular vs ecclesial).

It was decided for economic reasons that a maximum of 25% of all employees of each randomly selected SW and at most 50% of all residents of each randomly selected SH will be assessed. Thus, the number of SW and the number of SH to be randomly selected from each specific stratum resulted directly from the randomisation process. Non-participating institutions were replaced by the subsequent institution in the random selection.

### Recruitment of study participants

Potential study participants are randomly selected from an anonymous list of all employees/residents with ID of a randomly selected SW/SH institution. The staff of the service providing institution is asked to inform the potential study participants and their legal guardians about

the study and to ask for permission to be contacted by research staff. Subsequently to this consent, the research staff obtains written informed consent from the adult with ID or, if necessary, from their legal guardian.

The key carer in the living environment (eg, a relative or a staff member of the SH) and (if applicable) the physician that prescribes the PM are contacted by the research staff and invited for participation. The key carers meet the inclusion criteria if they are acquainted with the person with ID for at least 3 months and are in contact at least once a week or if they are acquainted for at least 2 years. There is no personal interview with the adults with ID conducted due to the inclusion of people with severe and profound levels of ID.

After informed consent is obtained by the study participants, interviews are conducted with the key carers in the living environment predominantly. If the adult with ID has a PM prescription in the past 4 weeks, the physician (eg, psychiatrist, neurologist) is interviewed via telephone interview.

According to sample size calculation,  $n=109$  study participants using PM will be recruited in order to assess quality of PM with sufficient accuracy. Assuming a PM prevalence of 30%, an estimated total number of  $n=200$  study participants via SW and  $n=400$  via SH will be contacted to obtain data of approximately  $n=131$  study participants recruited through SW and  $n=232$  participants through SH (figure 1).

### Primary outcome measure

#### Quality of psychotropic medication treatment

If the adults with ID had a PM prescription of at least one of the following six substance classes in the past 4 weeks: neuroleptics, antidepressants, benzodiazepines, lithium, anxiolytics/sedatives/hypnotics (excluding benzodiazepines) and/or antiepileptics (if not solely used for the treatment of an epilepsy), the *Interview for Assessing the Quality of Psychopharmacological Treatment of Adults with Intellectual Disabilities (IQP)*\* is conducted. The semi-structured interview assesses the prescription practice of PM in adults with ID. It is based on current guidelines of PM prescription in adults with ID and has been developed with the guidance of three clinical experts in the psychopharmacological treatment of people with ID. The interview comprises 13 quality indicators that are assigned to one of seven domains: (A) general topics; (B) diagnostics and indication; (C) information and consent; (D) prescription practice; (E) monitoring; (F) 'off-label' use and (G) PRN medication. Interviews are conducted with the key carer in the living environment and the prescribing physician with the use of all available sources of information (eg, records, hospital reports). The responses of both interviewees are summarised for each quality indicator by the interviewer and rated on a separate IQP assessment sheet that comprises all 13 quality indicators including a four-point rating scale from '1 – not fulfilled' to '4 – fulfilled' and the option '99 – not enough information'. In addition, seven indicators have the rating option '98 – not applicable'. If applicable, an integrated rating based on both, the carers' and the physicians' responses, is carried out by the interviewer.

### Other measures

#### Mental health service utilisation

Mental health service utilisation is assessed by a questionnaire based on the German version of the *Client Socio-Demographic and Service Receipt Inventory*.<sup>30</sup> If applicable, short descriptions of current problem behaviour and diagnoses of mental disorders are recorded, as well as the use of inpatient and outpatient health services and community-based services in the past 3 months. In addition, currently prescribed medication is recorded and any use of psychiatric and psychotherapeutic services during the lifetime. Data are obtained by all available sources including the information of interviewees and records (if available).

If the adults with ID had at least one PM prescribed in the past 4 weeks, medication parameters, side effects and the satisfaction with and quality of these services is assessed.

#### Objective parameters of psychotropic medication

The parameters of PM are obtained by the *Psychotropic Medication Interview (PMI)*\* for each prescribed PM in the past 4 weeks. Classification of PM is based on the Anatomical Therapeutic Chemical – Classification system.<sup>31</sup> Items of the PMQ comprise, among others, the trade name, agent, central pharma number, substance class, dosage form, daily dose, possible changes in dosage in the past year, reasons for possible dosage change, overall duration of treatment, use as PRN medication, 'off-label' use, psychiatric disorders and/or problem behaviours and/or target symptoms being treated, period of prescription, monitoring of parameters, medication intake refusals over the past year, other medication prescribed for the treatment of psychiatric symptoms/problem behaviour/target symptoms and specialisation of the first and last prescribing physician. Information is obtained by all available sources, for example, the key carer in the living environment (27 items), the prescribing physician (16 items) and in-depth record analysis.

#### Side effects of psychotropic medication

The *Liverpool University Neuroleptic Side Effect Rating Scale*<sup>32</sup> is used to assess side effects of the PM in the past 4 weeks. The questionnaire was translated into German and backtranslated according to the guidelines of Clinical Outcomes at Oxford University Innovation Limited. It was pilot tested and, with permission of the author, adapted as a proxy measure\*. The questionnaire comprises 51 items, 41 known side effects of neuroleptics and 10 red herrings, each rated on a five-point rating scale ranging from '0 – not at all' to '4 – very much'. The category 'unknown' was added for each item for the use as a proxy measure. The 10 red herrings items are not used in this study. Items can be assigned to one of the following seven subscales: extrapyramidal side effects; anticholinergic side effects; other autonomic; allergic reactions; psychic side effects; hormonal side effects and miscellaneous. The questionnaire is completed by the key carer.

### Satisfaction with psychotropic medication

The *Patient Satisfaction with Psychotropic scale*<sup>33 34</sup> is used to assess the effectiveness, evaluation and satisfaction with the PM and the patient-physician relationship. With permission of the author, this nine-item questionnaire was translated into German and adapted as a proxy measure to be completed by the key carer in the living environment\*. In addition, three items about the relationship between the key carer and the physician were added. All items are rated on a five-point rating scale ranging from '1 – not at all' to '5 – very much so' or with a similar content.

### Side effects and evaluation of psychotherapy

If a psychotherapeutic treatment was used in the past 3 months, possible therapy side effects and the overall evaluation of the psychotherapy is assessed by a small number of items based on the *Inventory for the Negative Effects of Psychotherapy*.<sup>35</sup> The adapted questionnaire consists of two domains: (A) 'side effects' comprising seven items rated on a four-point rating scale ranging from '0 – not at all applicable' to '3 – entirely applicable' and (B) 'evaluation' including three items about the evaluation of the psychotherapy rated on a five-point rating scale ranging from '1 – not at all' to '5 – entirely'. The questionnaire is completed by the key carer.

### Assessment of mental health service provision

The self-developed interview *Assessment of Mental Health Service Provision of People with Intellectual Disabilities*\* is used to assess the carers and physicians opinions regarding PM treatment and mental health service provision of people with ID. The interview comprises quantitative and qualitative parts and is available in two versions. The carers version of the interview consists of six items, the physician's version consists of nine items. Carers and physicians are asked to rate their consent with the statement that PM is used too often and non-compliant with current guidelines on a four-point rating scale ranging from '1 – yes, definitely' to '4 – no, not at all'. Both are asked via open questions about their opinions regarding the reasons for PM overuse and possibilities to reduce the PM usage in this population. Furthermore, physicians are asked why they think the PM treatment of this population is viewed critically and the carers are asked for their opinion regarding the role of PM in the daily care of people with ID. Two further items capture the carers and physicians ratings of the quality of PM and mental healthcare provision of people with ID in general based on a six-point rating scale from '1 – very good' to '6 – very bad'. In addition, physicians are asked to compare both kinds of mental healthcare provision of people with ID to the service provision of the general population based on a six-point rating ranging from '1 – much better' to '6 – much worse'.

### Individual factors, societal factors and health services system factors

The revised *Psychiatric Assessment Schedule for Adults with Developmental Disability Checklist*<sup>36</sup> is a screening instrument for life events and psychiatric symptoms in people

with ID. The German version of this 25 items questionnaire<sup>37</sup> is used. Severity and frequency of psychiatric symptoms during the past 4 weeks is rated by the key carer in the living environment. Items are scored with 0, 1 or 2 points, which are summarised in five subscores. Subscores are combined to three subscales: possible organic cause, affective and neurotic disorder and psychotic disorder, with each having a threshold score that indicate further assessment.

The *Aberrant Behaviour Checklist-Community*<sup>38</sup> is used to assess inappropriate behaviour of the adult with ID in the past 4 weeks. The German version of this 58 items questionnaire<sup>37</sup> is used. It is rated by the key carer in the living environment. All items target the frequency and severity of a specific problem behaviour and are rated on a four-point rating scale from '0 – no problem at all' to '3 – severe problem'. Items can be allocated to one of the five subscales: (1) irritability, agitation, crying; (2) lethargy, social withdrawal; (3) stereotypic behaviour; (4) hyperactivity, non-compliance and (5) inappropriate speech.

Basic sociodemographic data of the adult with ID, the key carer in the living environment, the physician and/or psychotherapist are obtained in a short interview with the key carer and the physician (if applicable).

In addition, basic parameters of the participating SH and basic data of the service provision area are obtained in an interview and via internet search.

### Interview procedure

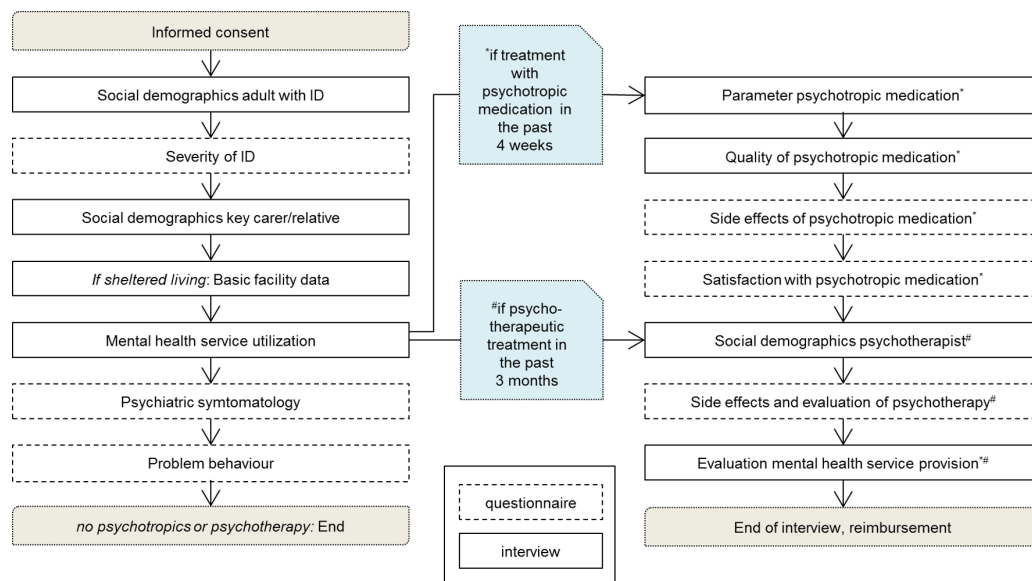
An overview of all parameters and the whole interview procedure of the PROMPT-ID study is given by [figure 2](#) regarding the interview procedure with the key carer.

After the informed consent has been obtained, the telephone interview with the physician starts with basic social demographics of the interviewee. Subsequently the parameters of all currently prescribed PM of the adult with ID are obtained. Afterwards the quality of PM is assessed with the newly developed IQP interview and the physicians' opinion regarding the mental health service provision of people with ID is ascertained. After the end of the telephone interview with the physician the reimbursement is transferred.

### Data analysis

Prevalence of PM and psychotherapeutic treatment of people with ID will be calculated as periodic prevalence: the number of people which have had PM or psychotherapeutic treatment in the past 3 months prior to data collection is divided by the total number of people with ID screened for PM prescription.

To compare adults with ID with and without PM regarding the parameters psychiatric symptomatology, problem behaviour and sociodemographic variables  $\chi^2$  tests and t-tests will be carried out. Descriptive statistics are used to describe the quality of PM prescription based on the interviewers' ratings. Logistic regression analysis will be used to identify predictors for use versus non-use



**Figure 2** Parameters and interview procedure—carer.

of PM or psychotherapeutic treatment and to identify potential predictors of good clinical practice in PM of adults with mild to profound ID. The potential predisposing variables: age, sex, degree of ID, existence of a legal guardian and living situation will be analysed. As parameters that indicate the need for PM or psychotherapeutic treatment, the following variables will be analysed: prevalence of a specific mental disorder; problem behaviour, the existence of previous or current diagnoses of psychiatric disorders and parameters concerning the provision area (eg, number of settled down psychotherapists in the provision area, distance to specialised hospitals, etc).

#### Quality assurance, monitoring of recruitment and data collection

Prior to data collection, an interviewer training in all relevant measures and a pilot study was conducted. To ensure a comparable interview procedure across interviewers, a detailed interview implementation description is provided in an interviewer manual.

During the study implementation, the study team is advised by three clinical experts. Expert meetings in the beginning and in the end of the study implementation ensure a high methodological standard. Recruitment status of institutions and of study participants is recorded monthly.

The questionnaires and all other PROMPT-ID study materials are stored in locked cupboards during study implementation. The original questionnaires are transferred to the archive afterwards and are destroyed 10 years after study completion. The collected data are transferred to and analysed using the statistical programme IBM SPSS Statistics, V.25. Quality control monitoring of the database is realised during the study implementation. Prior to locking the database, a second data entry of 10% randomly selected cases is carried out.

A statistician will support the project team in doing the complex statistical analyses.

#### Patient and public involvement

No person with ID and/or their legal guardians or key carers were involved in the design of the PROMPT-ID study directly. However, the research team is experienced in the conduction of studies in the field of ID. They designed the PROMPT-ID study based on the results of the previously conducted ‘Mental healthcare provision for adults with intellectual disability and a mental disorder’ (MEMENTA) study and followed the advice from practice that PM treatment in this population is questionable. The research team is advised by three clinical experts with decades-long experience in this area and the advice of staff of the SH uttered during pilot testing was implemented. The people with ID are recruited via SW and SH institutions and their informed consent and/or that of their legal guardian (if applicable) are obtained. Subsequently, informed consent of the key carers in the living environment and of the PM prescribing physicians is obtained. Results will be disseminated in a short information brochure to the care-taking institutions and study participants.

#### Allowance

SW receive a reimbursement of €10 for every successfully imparted study participant. Staff of SH and relatives receive a reimbursement of €20 for every conducted interview and physicians receive a reimbursement of €100 for every conducted telephone interview.

#### DISCUSSION

The prevalence and quality of mental health service provision of adults with ID is an understudied topic that lacks

methodologically sound studies. This applies especially to the often criticised PM treatment of this clientele, for example, there is no current study targeting the adherence to current PM prescription guidelines and data regarding the prevalence and quality of psychotherapeutic treatment of adults with ID is hardly available. In Germany, reasons for this paucity might be the separation between the service providing systems of psychiatry and therapeutic paedagogy and the general difficulties faced when conducting studies in this area, for example, there are no regional registers of this population in Germany available. The elaborate recruitment process might further be challenging in respect of the collaboration with the caretaking institutions, legal guardians, relatives, service providing staff and physicians.

Despite these barriers, the cross-sectional, epidemiological PROMPT-ID study aims to collect information about the current mental healthcare service provision in adults with mild to profound levels of ID in Germany. The study complies with high methodological standards. Initially, cooperating institutions are stratified to a cluster sample by type of service provider and size of the SW or type of SH, respectively. Subsequently, a two-stage random sampling of facilities and study participants is realised. The measures used in this study are either well-established or newly developed in guidance of clinical experts. Interviews are conducted with the carers in the living environment and the physician that prescribes the PM currently.

As there are no regional registers of adults with ID available, the sampling procedure is limited by the exclusion of people with ID not using professional services in at least one of the areas living or working. A further limitation of the study is that self-reports are not possible because of the study design that includes adults with severe and profound levels of ID. However, strengths of this study include the following: a pilot study was conducted beforehand, the study team is advised by a team of clinical experts and psychometric properties of key outcome measures are to be tested after sufficient data are collected.

Findings will fill the lack of representative data that is urgently needed in this often criticised health service area. The PROMPT-ID study will add information about the mental health service provision of people with ID in Germany, such as prevalence of PM and psychotherapeutic interventions and the quality of mental health service provision in this population. The identified predictors of good PM prescription quality create an empirical data basis that enables political discussions to provide a high-quality personalised mental health service provision of adults with ID. Furthermore, this study will encourage further research in this area, which will enable a comparison of different regions or countries.

The results will be published in journals and presented at national and international conferences. Findings will also be disseminated in a short and comprehensible summary to the care-taking institutions and study participants.

## Symbol legend

Outcome measures supplemented with an asterisk (\*) are unpublished.

**Acknowledgements** The authors acknowledge support by the Open Access Publication Funds of the SLUB/TU Dresden. The authors are grateful for the language proofread of the manuscript by Tyler Bassett. Without the support of the participating sheltered workshops, sheltered housing institutions and the support of the key carers, relatives, legal guardians and physicians, the conduction of this study would not have been possible. We deeply appreciate their support.

**Contributors** MS and AK are responsible for project conception and wrote the research proposal. AK drafted the manuscript based on the research proposal. JD and MS reviewed this manuscript draft critically and contributed important improvement suggestions to the conceptualisation of the final manuscript. AK, JD and MS reviewed the final manuscript critically, and approved it.

**Funding** The PROMPT-ID study is funded by the German Research Foundation (DFG, SCHU1346/41).

**Competing interests** None declared.

**Patient consent** Obtained.

**Ethics approval** The study has been approved by the Ethics Committee of the Technische Universität Dresden.

**Provenance and peer review** Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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## REFERENCES

- Maulik PK, Mascarenhas MN, Mathers CD, *et al*. Prevalence of intellectual disability: a meta-analysis of population-based studies. *Res Dev Disabil* 2011;32:419–36.
- Cooper SA, Smiley E, Morrison J, *et al*. Mental ill-health in adults with intellectual disabilities: prevalence and associated factors. *Br J Psychiatry* 2007;190:27–35.
- Schützwohl M, Koch A, Koslowski N, *et al*. Mental illness, problem behaviour, needs and service use in adults with intellectual disability. *Soc Psychiatry Psychiatr Epidemiol* 2016;51:767–76.
- Tsiouris JA, Kim SY, Brown WT, *et al*. Prevalence of psychotropic drug use in adults with intellectual disability: positive and negative findings from a large scale study. *J Autism Dev Disord* 2013;43:719–31.
- Sheehan R, Hassiotis A, Walters K, *et al*. Mental illness, challenging behaviour, and psychotropic drug prescribing in people with intellectual disability: UK population based cohort study. *BMJ* 2015;351:h4326.
- Bowring DL, Totsika V, Hastings RP, *et al*. Prevalence of psychotropic medication use and association with challenging behaviour in adults with an intellectual disability. A total population study. *J Intellect Disabil Res* 2017;61:604–17.
- Doan TN, Lennox NG, Taylor-Gomez M, *et al*. Medication use among Australian adults with intellectual disability in primary healthcare settings: a cross-sectional study. *J Intellect Dev Disabil* 2013;38:177–81.
- Hennicke K. Psychopharmaka in Wohnstätten der Behindertenhilfe Vermutungen über einer zunehmend unerträgliche Situation. Hennicke K, ed. *Psychopharmaka in der Behindertenhilfe - Fluch oder Segen? Dokumentation der Arbeitstagung der DGSGB am 9.11.2007 in Kassel*: Kassel, Germany. Berlin: Eigenverlag der DGSGB, 2008:4–22.
- Häßler F, Thome J, Reis O. Polypharmacy in the treatment of subjects with intellectual disability. *J Neural Transm* 2015;122:S93–100.
- Holden B, Gitlesen JP. Psychotropic medication in adults with mental retardation: prevalence, and prescription practices. *Res Dev Disabil* 2004;25:509–21.
- Paton C, Bhatti S, Purandare K, *et al*. Quality of prescribing of antipsychotic medication for people with intellectual disability under

- the care of UK mental health services: a cross-sectional audit of clinical practice. *BMJ Open* 2016;6:e013116.
12. Perry BI, Cooray SE, Mendis J, et al. Problem behaviours and psychotropic medication use in intellectual disability: a multinational cross-sectional survey. *J Intellect Disabil Res* 2018;62(2):140–9.
  13. Scheifes A, Egberts TC, Stolker JJ, et al. Structured Medication Review to Improve Pharmacotherapy in People with Intellectual Disability and Behavioural Problems. *J Appl Res Intellect Disabil* 2016;29:346–55.
  14. Seidel M. Psychopharmaka bei Menschen mit geistiger Behinderung. Ein kritischer Problemaufriss. Seidel M, ed. *Psychopharmaka bei Menschen mit geistiger Behinderung - Erfüllte und unerfüllte Versprechen - Dokumentation der Arbeitstagung der DGSGB am 12.11.2010 in Kassel*. Kassel, Germany. Berlin: Eigenverlag der DGSGB, 2011:4–21.
  15. Deb S, Kwok H, Bertelli M, et al. Guideline Development Group of the WPA Section on Psychiatry of Intellectual Disability. International guide to prescribing psychotropic medication for the management of problem behaviours in adults with intellectual disabilities. *World Psychiatry* 2009;8:181–6.
  16. de Leon J, Greenlee B, Barber J, et al. Practical guidelines for the use of new generation antipsychotic drugs (except clozapine) in adult individuals with intellectual disabilities. *Res Dev Disabil* 2009;30:613–69.
  17. National Institute for Health and Care Excellence. *Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges*. London: NICE, 2015. NICE guideline.
  18. Raghavan R, Patel P. Ethical issues of psychotropic medication for people with intellectual disabilities. *Adv Ment Health Intellect Disabil* 2010;4:34–8.
  19. Trollor JN, Salomon C, Franklin C. Prescribing psychotropic drugs to adults with an intellectual disability. *Aust Prescr* 2016;39:126–30.
  20. Bhaumik S, Gangadharan S, Hiremath A, et al. Psychological treatments in intellectual disability: the challenges of building a good evidence base. *Br J Psychiatry* 2011;198:428–30.
  21. Koslowski N, Klein K, Arnold K, et al. Effectiveness of interventions for adults with mild to moderate intellectual disabilities and mental health problems: systematic review and meta-analysis. *Br J Psychiatry* 2016;209:469–74.
  22. Thompson Prout H, Browning BK. Psychotherapy with persons with intellectual disabilities: a review of effectiveness research. *Adv Ment Health Intellect Disabil* 2011;5:53–9.
  23. Vereenoghe L, Langdon PE. Psychological therapies for people with intellectual disabilities: a systematic review and meta-analysis. *Res Dev Disabil* 2013;34:4085–102.
  24. Beail N. *Psychological therapies and people who have intellectual disabilities*. Leicester: British Psychological Society, 2016.
  25. Glasenapp J, Schäper S, eds. *Barrierefreie Psychotherapie. Möglichkeiten und Grenzen der psychotherapeutischen Versorgung von Menschen mit Intelligenzminderung. Dokumentation der Fachtagung der DGSGB am 11. März 2016 in Kassel*. Kassel, Germany. Berlin: Eigenverlag der DGSGB, 2016.
  26. Idusohan-Moizer H, Sawicka A, Dendle J, et al. Mindfulness-based cognitive therapy for adults with intellectual disabilities: an evaluation of the effectiveness of mindfulness in reducing symptoms of depression and anxiety. *J Intellect Disabil Res* 2015;59:93–104.
  27. Kremitztl K, Engenhorst A, Simon T, et al. Zur psychotherapeutischen Versorgung erwachsener Menschen mit Intelligenzminderung in Baden-Württemberg. *Psychotherapeutenjournal* 2018:135–43. German.
  28. Kufer K, Bengel J. Psychotherapie für Menschen mit geistiger Behinderung – Hintergründe. In: Glasenapp J, Schäper S, eds. *Barrierefreie Psychotherapie. Möglichkeiten und Grenzen der psychotherapeutischen Versorgung von Menschen mit Intelligenzminderung. Dokumentation der Fachtagung der DGSGB am 11. März 2016 in Kassel*. Kassel, Germany. Berlin: Eigenverlag der DGSGB, 2016.
  29. Sappok T, Voß T, Millauer E, et al. Psychotherapie bei Menschen mit Intelligenzminderung. Theoretischer Hintergrund und praktische Umsetzung. *Nervenarzt* 2010;81:827–36. German.
  30. Roick C, Kilian R, Matschinger H, et al. Die deutsche Version des Client Sociodemographic and Service Receipt Inventory - Ein Instrument zur Erfassung psychiatrischer Versorgungskosten. *Psychiatr Prax* 2001;28 (Suppl 2):S84–90.
  31. Fricke U, Günther J, Niepraschk-von Dollen K, et al. *Anatomisch-therapeutisch-chemische Klassifikation mit Tagesdosen, Amtliche Fassung des ATC-Index mit DDD-Angaben für Deutschland im Jahre 2017 14. aktualisierte amtliche Fassung*. Berlin, 2017.
  32. Day JC, Wood G, Dewey M, et al. A self-rating scale for measuring neuroleptic side-effects. Validation in a group of schizophrenic patients. *Br J Psychiatry* 1995;166:650–3.
  33. Gasquet I, Villemintot S, Estaquio C, et al. Construction of a questionnaire measuring outpatients' opinion of quality of hospital consultation departments. *Health Qual Life Outcomes* 2004;2:43.
  34. Nordon C, Falissard B, Gerard S, et al. Patient satisfaction with psychotropic drugs: Validation of the PAtient SAtisfaction with Psychotropic (PASAP) scale in patients with bipolar disorder. *Eur Psychiatry* 2014;29:183–90.
  35. Ladwig I, Rief W, Nestoriuc Y. Welche Risiken und Nebenwirkungen hat Psychotherapie? - Entwicklung des Inventars zur Erfassung Negativer Effekte von Psychotherapie (INEP). *Verhaltenstherapie* 2014;24:252–63. German.
  36. Moss S. *PAS-ADD checklist*. Brighton: Pavilion Pub, 2002.
  37. Zeilinger EL, Weber G, Haveman MJ. Psychometric properties and norms of the German ABC-Community and PAS-ADD Checklist. *Res Dev Disabil* 2011;32:2431–40.
  38. Aman MG, Singh NN. *Aberrant behaviour checklist—community*. East Aurora, NY: Slosson Educational Publications, Inc, 1986.