ABSTRACT

Introduction: The study ‘Mental healthcare provision for adults with intellectual disability and a mental disorder’ (MEMENTA) is a cross-sectional epidemiological study carried out in three different regions of Germany. Its main aim is to assess the prevalence of mental disorders in adults with intellectual disability (ID) as well as quality of mental healthcare for this population.

Methods and analysis: The target population are persons aged between 18 and 65 years with a mild or moderate ID. The study population will be recruited through service providers. A representative sample is realised by two-stage sampling. First, institutions providing services for people with ID (sheltered workshops) are selected in a stratified cluster sampling, with strata being (1) types of service-providing governmental organisations and (2) sizes of their sheltered workshops. Then persons working in selected sheltered workshops are selected by simple random sampling.

An estimated number of 600 adults with ID will be included. Information will be obtained from the group leaders in the sheltered workshops, informal carers or staff members in sheltered housing institutions and the person with ID. Besides the main outcome parameter of psychiatric symptomatology and problem behaviour, other outcome parameters such as needs for care, quality of life, caregiver burden, health services utilisation and costs for care are assessed using well-established standardised instruments. If a comorbid mental disorder is diagnosed, quality of mental healthcare will be assessed with open questions to all interview partners and, in addition, problem-focused interviews with a small subgroup. Analyses will be carried out using quantitative and qualitative methods.

Ethics and dissemination: Approval of all three local ethics committees was obtained. Research findings will add much needed empirical information in order to improve services provided to this vulnerable group of patients.

Trial Registration number: NCT01695395.

Strenghts and limitations of this study

- Limitations include the sampling frame of this study being limited to listings of institutions providing services for people with ID, thus findings may not be generalised to those who are not at all in contact with these institutions.
- Strengths include implementation of a complex sampling method using a cluster (institution) sampling to prevent avoidable selection bias in the three different study sites.
- Further strengths are the use of well-established instruments such as the PAS-ADD Checklist for screening for symptoms of psychiatric illness and the Mini PAS-ADD for an in-depth assessment of mental health problems in this under-studied population.

BACKGROUND

According to the World Health Report, the overall prevalence of intellectual disability (ID) varies between 1% and 3%. The vast majority of cases (approximately 95%) are mild or moderate.1

Mental health problems in adults with ID is a widely understudied topic. The few existing studies on the prevalence of mental ill health in adults with ID show a wide discrepancy in reported prevalence rates which range from 7% to 97%.2 One of the methodically most elaborate studies from the UK...
reports population-based point prevalence rates varying between 15.7% and 40.9%, depending on the diagnostic criteria used. In general, there is a growing consensus that adults with ID are affected by mental ill health at least as often as adults without ID and that there is an increased vulnerability to develop a mental disorder among people with ID.

During the past years, stimulated by the ratification of the UN Convention on the Rights of Persons with Disabilities (UNCRPD), mental healthcare provision for mentally ill adults with ID has been subject to critical reflections. In Germany, experts working in the field stated that mental health services provision to this group was inadequate, indicated, for example, by not sufficiently equipped general psychiatric institutions and a shortage of specialised ID mental health services. This indicates that the current situation in Germany might not be in line with the UNCRPD which emphasises that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability (Art. 25).

Thus, there is growing agreement across Germany that mental health services provision and mental healthcare for adults with ID and mental ill health has to be improved. However, there are only scant empirical data allowing well-founded measures aiming to improve health services provision for this specific population.

The MEMENTA-Study (“Mental healthcare provision for adults with intellectual disability and a mental disorder”) is the first to target this topic in Germany. It has two main aims. The first is to provide data on the prevalence of mental ill health among adults with mild or moderate ID. The second is to identify specific needs and problems among intellectual disabled adults with a mental disorder compared with intellectual disabled adults without a mental disorder.

METHODS AND DESIGN

The MEMENTA-Study is a cross-sectional epidemiological multicentre study funded by the Federal Ministry of Education and Research (BMBF, Grant ID Number: 01GY1134). Settings include urban and rural areas in the Regional Area Dresden, the Rhine Neckar Metropolitan Region and Bavarian Swabia. The three study sites are the Mental Health Services Research Groups at the Department of Psychiatry and Psychotherapy, Carl Gustav Carus University Hospital, Technische Universität Dresden; at the Central Institute of Mental Health, Medical Faculty Mannheim/Heidelberg University and at the Department of Psychiatry II, Ulm University, Bezirkskrankenhaus Günzburg. Recruitment started in October 2012. The estimated date of the last participant in is January 2014.

Participants

Inclusion and exclusion criteria

Inclusion criteria were defined as follows: adults aged between 18 and 65 years with a mild or moderate ID. Persons with severe or profound ID or borderline intellectual functioning are excluded.

Severity of ID is assessed by a self-developed standardised assessment sheet based on the definition of ID by the American Association on Intellectual and Developmental Disabilities (AAIDD) and on well-defined criteria of adaptive behaviour impairment in different degrees of ID. The assessment sheet, to be rated by staff and key carer or relative, asks about cause and age of the onset of cognitive impairment as well as the presence of an established diagnosis of ID. Furthermore, it comprises six items assessing the level of functioning in three skill domains (conceptual, practical and social) on four-point scales indicating different levels of disability (A=severe ID, B=moderate ID, C=mild ID, D=learning disability). A person meets the inclusion criteria if their skills are rated as mild or moderately impaired due to their ID in at least two of the three skill domains.

Recruitment

Since there are no regional registers of adults with intellectual disabilities that can be used in this study, the population will be accessed through service providers. In Germany, services for persons with ID are roughly divided into services for accommodation (e.g., residential accommodation) and services for employment (e.g., sheltered workshop). The vast majority of persons with a mild or moderate ID between 18 and 65 years in supported accommodation work in a sheltered workshop, while conversely not all of those working in a sheltered workshop use services for accommodation. In order to achieve best coverage between target population and sampling frame with reasonable expense, we decided to use registers of sheltered workshops as a sampling frame.

Recruitment of sheltered workshops

A systematic and comprehensive search was conducted in order to identify all sheltered workshops for adults with ID in each study region. At this stage, 56 institutions were identified in the Regional Area Dresden, 15 institutions in the Rhine Neckar Metropolitan Region and 28 institutions in Bavarian Swabia.

In each study region, the identified sheltered workshops were stratified by (1) types of service-providing non-governmental organisations (e.g., the German Catholic Church’s welfare association Caritas) and (2) sizes of their sheltered workshops. It was decided for economic reasons that a maximum of 15% of all employees of each randomly selected sheltered workshop will be assessed, so that the number of sheltered workshops to be randomly selected from each specific stratum resulted directly from the randomisation process. Under this condition and given the intended sample sizes, 15 institutions were selected in the Regional Area Dresden, 15 in the Rhine Neckar Metropolitan Region and 11 in Bavarian Swabia.
Recruitment of study participants

Potential study participants are randomly selected from an anonymous list of all employees with ID working in each randomly selected sheltered workshop and then contacted by the staff of the sheltered workshops, informed about the study and asked whether research staff may contact them. If the adult with ID agrees, he or she will be informed in detail about the study by the research staff, including information on the background of the study, confidentiality and formal aspects like scheduling of interviews.

Informed consent is then obtained by the person with ID themselves or, if necessary, by their legal guardian. Legal guardians are either contacted directly by the research staff, for example, at meetings in the sheltered workshop, or by the staff of the sheltered workshop, depending on organisational conditions. Information materials and consent forms as well as research staff’s contact information are given or sent to the legal guardians with request for reply. Subsequently, the group leader in the sheltered workshop and a key carer (ie, a relative or a staff member in sheltered housing institutions) are contacted by the research staff to inform them about the study and to invite them for participation.

Interviews are conducted, if possible, with the person with ID themselves, the group leader in the sheltered workshop and the key carer (cf. table 1). Interviews per study participant are conducted in closely timed intervals. If not otherwise requested by the person with ID, interviews with adults with ID take place during working hours and are scheduled in consultation with sheltered workshop staff.

Outcome measures

Psychiatric symptomatology and problem behaviour

The German version of the Psychiatric Assessment Schedule for Adults with Developmental Disability Checklist (Revised) (PAS-ADD Checklist)\textsuperscript{10,22} is used to screen for symptoms of psychiatric illness. It was designed to be easily completed by untrained users, has shown good reliability and utility and is considered the best measure available for people with ID at risk of having a psychiatric disorder.\textsuperscript{22-25} Twenty-five items tapping into severity and frequency of psychiatric symptoms during the past 4 weeks are rated on a four-point scale by the group leaders in the sheltered workshops and the key carers. Ratings for each item are scored with 0, 1 or 2 points and summarised into five scores. These scores are

<table>
<thead>
<tr>
<th>Parameter and instrument</th>
<th>Interviewee Person with ID</th>
<th>Group leader*</th>
<th>Key carer†</th>
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<tbody>
<tr>
<td>Level of intellectual disability (ID)</td>
<td></td>
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<tr>
<td>Intellectual Disability Level Assessment Sheet\textsuperscript{7}</td>
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<tr>
<td>Psychiatric Assessment Schedule for Adults with Developmental Disability Checklist (PAS-ADD Checklist)\textsuperscript{10}</td>
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<td>Mini PAS-ADD\textsuperscript{11}</td>
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<td>Problem behaviour</td>
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<td>Aberrant Behavior Checklist-Community (ABC-C)\textsuperscript{12}</td>
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<td>Needs</td>
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<tr>
<td>Camberwell Assessment of Need for Adults with Developmental and Intellectual Disabilities (CANDID)\textsuperscript{13}</td>
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<td>Quality of life—adult with ID</td>
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<td>WHO Quality of Life Questionnaire; Short Version (WHOQOL-BREF)\textsuperscript{14}; Disability Module (WHOQOL-Dis)\textsuperscript{15,16}</td>
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<td>X</td>
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<td>WHO Quality of Life Questionnaire; Easy Read Short Version (WHOQOL-BREF-ERV) Disability Module—Easy Read Version (WHOQOL-Dis-ERV)</td>
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<td>X</td>
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<tr>
<td>Health services utilisation and costs</td>
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<tr>
<td>Client Socio-Demographic and Service Receipt Inventory (CSSRI)\textsuperscript{17}</td>
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<tr>
<td>Related caregiver burden and costs for care</td>
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<tr>
<td>Involvement Evaluation Questionnaire (IEQ)\textsuperscript{18,19}</td>
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<td>Financial Burden Family Sheet\textsuperscript{20}</td>
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<td>Quality of life—related caregiver</td>
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<td>Open questions</td>
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*Group leader in the sheltered workshop.
†Key carer (related caregiver or staff in the sheltered housing institution).

combined to three subscales: affective or neurotic disorder, possible organic condition and psychotic disorder, which each have a threshold score.

If PAS-ADD Checklist subscale values are equal or above specified thresholds or if an existing psychiatric symptomatology is suggested by (1) behaviour described to which scored items are not applicable and/or (2) current intake of psychotropic drugs and/or (3) any current or lifetime psychiatric disorder, further assessment is carried out. Thus, we used the German version of the semistructured Mini PAS-ADD to be completed by the group leader in the sheltered workshops and the key carer. It is derived from the PAS-ADD semistructured clinical interview and assesses primary psychiatric symptoms based on the frequency and severity of behaviour during the past 4 weeks. Coding is guided by a glossary of symptom definitions. The Mini PAS-ADD consists of 66 items. Fifteen scores can be computed, which are combined to seven subscales: psychosis, mania, pervasive developmental disorder (autism), depression, unspecified disorder (including dementia), anxiety disorder and obsessive compulsive disorders.

The German version of the Aberrant Behavior Checklist—Community (ABC-C) is used to assess problem behaviour. In this 58-item questionnaire, the frequency and severity of problem behaviour during the past 4 weeks is rated by the group leader and the key carer, yielding five subscale scores: (1) irritability, agitation, crying; (2) lethargy, social withdrawal; (3) stereotypic behaviour; (4) hyperactivity, non-compliance and (5) inappropriate speech.

Needs
A semistructured interview, the Camberwell Assessment of Need for Adults with Developmental and Intellectual Disabilities (CANDID), is used to assess needs from the perspectives of the person with ID itself, the group leader in the sheltered workshops and the key carer. With authorisation from the rights holders the CANDID was translated into German by the MEMENTA-Study Group and then back translated by a psychiatrist with native English origin. The comparison of the original and the back-translated version showed no substantial differences. Minor differences were optimised. The CANDID measures needs in 25 areas (eg, accommodation, food, general physical health, major mental health problems) indicating no, met or unmet needs (rated 0, 1 or 2) and whether formal or informal help is received. High CANDID summary scores (eg, total number of needs) indicate high need for support.

Quality of life
The WHO Quality of Life-BREF (WHOQOL-BREF) is used together with the add-on module WHOQOL-Dis to assess quality of life (QoL) of the person with ID in the preceding 4 weeks. In this short version of the WHOQOL-100, four domains of QoL (physical, psychological, social relationships and environment) and two global ratings are covered by 26 items. The WHOQOL-Dis module consists of 13 disability specific items based on the three facets autonomy, discrimination and inclusion. WHOQOL-BREF and WHOQOL-Dis are completed by the group leader in the sheltered workshops and the key carer in order to assess their estimation of the subjective QoL of the person with ID.

Easy Read versions of the WHOQOL-BREF and WHOQOL-Dis were developed by the MEMENTA-Study Group and subsequently checked by an institution specialised in producing Easy Read material (Büro für Leichte Sprache). All advices and improvement suggestions made by the people with learning difficulties were implemented. These Easy Read versions are used to obtain self-rated subjective QoL of the caregiving relative of the person with ID.

Health services utilisation
An adapted version of the German version of the Client Socio-Demographic and Service Receipt Inventory (CSSRI) is used to assess the living condition, employment and income of the person with ID. In addition, the frequency and length of various health services utilisation in the preceding 3 months (eg, hospital inpatient, outpatient and complementary services used and medication prescribed) is assessed. Information is obtained by all available sources (eg, the records of the person with ID and information provided by all interviewees).

Caregiver burden and costs for care
An adapted version of the Involvement Evaluation Questionnaire (IEQ) is used to assess caregiver burden. This questionnaire is answered by a caregiving family member and measures the encouragement and care given to their relative with ID, their relationship and problems between them, coping and subjective burden during the past 4 weeks. The IEQ includes 27 items yielding four subscales (tensions, supervision, worrying, urging) and one sum score over all items. The IEQ is complemented by items concerning physical and psychological problems of the main caregiver and possible involvement of other caregiving friends or family members.

The Financial Burden Family Sheet is used to assess disability or mental illness-related financial burden of informal caregivers and relatives of persons with ID. Information on families’ medical and non-medical expenditures and pretax family income is obtained.

Empowerment
The Empowerment Scale, which was designed to measure subjective feelings of empowerment, was adapted and translated into an Easy Read version by the MEMENTA-Study Group. The scale is composed of 25 statements with reference to the concept of empowerment. The person with ID shows their degree of
agreement with a particular statement by pointing on a visual four-point scale ranging from ‘strongly agree’ to ‘strongly disagree’. A sum score of all 25 items can be computed. Additionally, five questions capture inclusion, leisure activities and social activities of the person with ID.

Mental healthcare provision

Qualitative methods will be used to examine the quality of mental healthcare provision in two ways. First, open questions about satisfaction with mental healthcare, barriers to treatment and ways to improve mental healthcare will be asked to participants with ID and mental illness as well as their carers.

Second, in order to shed light on the subjective perceptions of mental healthcare, comprehensive problem-focused interviews will be conducted with six people with ID with at least moderate verbal skills who receive treatment for their mental health problems. Via open questions, the interviews will focus on personal views about mental illness, potential barriers to treatment and reasons for satisfaction or dissatisfaction with services. In order to receive a wide range of opinions, participants will be selected by means of purposive sampling using the criterion satisfaction with mental healthcare yielding two groups (high vs low satisfaction) with N=3 in each group.

Statistical analysis

First statistical analyses will be carried out after the inclusion of n=413 study participants. For the comparison of people with ID with and without comorbid mental health problems with regard to parameters such as needs and QoL, χ² tests and t tests will be used. To identify potential predictors of needs and QoL in adults with ID and mental health problems, exploratory regression analysis will be conducted. The qualitative analysis of the open questions concerning the mental healthcare provision and possible barriers into an appropriate healthcare system for adults with ID will be carried out via content analysis.

The problem-focused interviews will be analysed using MAXQDA according to the principles of qualitative content analysis.29

Sample size

Power calculation is based on the central aim to test whether there is a meaningful difference between the two population proportions of a specific need assessed using the CANDID. The sample size needed to detect a difference of 15% (p1−p2=0.15) with 90% power at a 5% level of statistical significance depends on the prevalence of psychiatric disorders and needs. Given a proportion of p1=0.45 and p2=0.60, sample size needed is 413, 447, 501, 586 and 734 for different prevalence rates of a psychiatric disorder according to Axis I of the Diagnostic and Statistical Manual of Mental Disorders (DSM) IV (35%, 30%, 25%, 20% or 15%).

Quality assurance, data monitoring and safety

Interviewer training

Data will be collected by skilled interviewers who received a 4-day interviewer training by experts prior to data collection. Interviewer training sessions covered transfer of knowledge on ID in general, on mental ill health in adults with ID, on specifics to be aware of when communicating with adults with ID and on all instruments used for data collection. Particular emphasis was given to the training of usage of Mini PAS-ADD11 and CANDID.13 To this end, several case vignette ratings were conducted and discussed in the group. To ensure comparable interview procedures across all participating centres, detailed instructions are provided in an interview manual. Possible exceptions to the regular interview procedure will be documented and discussed. An interview evaluation sheet on interview quality and other interview-specific information (eg, the interview situation in general, openness of the interviewee, interview interruptions) is completed by the interviewer after each conducted interview. In addition, case vignette ratings on the key instruments Mini PAS-ADD and CANDID are conducted and discussed monthly.

Monitoring of recruitment and data collection

All participating centres will update their recruitment status monthly and report them to the Dresden centre to ensure that recruitment is carried out as expected. Recruitment and data collection are also monitored in regular project meetings and telephone conferences.

Data safety

Data is stored online using the Research Electronic Data Capture (REDCap) software. Data is monitored, edited and redistributed by the independent Coordinating Centre for Clinical Trials (KKS) at the university hospital in Dresden.

Allowance

All interviewees receive a reimbursement for participation of €20/interview.

DISCUSSION

Mental health problems in adults with ID are a widely understudied topic. The reasons for this lack of existing research are twofold, first, because the subpopulation of mentally ill adults with ID was not in the focus of public or political awareness. Fortunately, this changed in recent years, not least as a result of the UNCRPD,7 resulting in increasing awareness for the mental healthcare situation of people with ID and calls for research.5 Second, research in this field is demanding and potential researchers are confronted with a number of methodological challenges. Thus larger epidemiological studies such as the ‘German Health Interview and Examination Survey for Adults’ (DEGS)30 do not assess the mental health status of adults with ID.
It is self-evident that the MEMENTA-Study, too, is confronted with a number of difficulties and thus with several limitations, which we try to reduce with appropriate strategies.

Identification of potential participants is difficult due to different reasons, for example, in Germany there is no national registry of people with ID which could be used to draw a random sample from. Thus, listings of institutions providing services for people with ID have to serve as a defined sample frame. In the MEMENTA-Study, all sheltered workshops in each study region were listed. Compared with sheltered houings, sheltered workshops are rather low-threshold services, thus ensuring to include both, persons living in community and institutional settings. However, sampling may be biased due to the fact that people not working in sheltered workshops are excluded, although this should affect people with severe or profound ID primarily.

A complex sampling method was chosen using a cluster (institution) sampling with probability proportional to the various service-providing non-governmental organisations and size, followed by a random sampling of persons of these institutions in order to prevent avoidable selection bias.

Another problem is that recruitment of participants is rather difficult, too, and can only succeed in cooperation with service-providing institutions. Obtaining agreement for participation of these institutions is known as one of the barriers for recruitment of potential participants. It is a strength of our study that umbrella organisations of institutions providing services either promised their support or declared their commitment in the study preparation phase, thus ensuring a high response rate at institutional level. However, even if this barrier can be overcome, recruitment is still impeded by ethical and legal requirements, for example, due to impaired comprehension skills only some possible participants will be able to consent on their own behalf while for others legal guardians have to decide on the involvement together with their client and in its best interest. Contacting legal guardians and obtaining consent will be time consuming. Albeit we will invest lots of efforts in avoiding refusals for participation, systematic reasons for refusal might affect the representativity of the sample. In order to get at least basic information, reasons underlying the refusal will be documented during the recruitment process.

Representativity of the sample might be limited by the fact that the administratively defined condition of ID which entitles people to access specialised services is not always consistent with a clinical diagnosis of ID, thus the described sampling strategy might lead to an overidentification of potential participants. We counter this risk by checking inclusion criterion of existing ID with a self-developed instrument that is, however, based on well-established conceptualisations and criteria. Thus, employees of the selected sheltered workshops that do not meet the defined inclusion criteria can be identified and excluded from the study.

The MEMENTA-Study shows the following strengths: with regard to the assessment of most important parameters of interest, the MEMENTA-Study uses well-established instruments such as the PAS-ADD Checklist for screening for symptoms of psychiatric illness, the Mini PAS-ADD11 for an in-depth assessment of mental health problems and the CANDID for assessing specific needs of adults with ID. To include subjective ratings by persons with ID in our study, Easy Read versions of well-established questionnaires have been developed, for example, the WHOQOL-BREF and the WHOQOL-DIS. Furthermore, all interviewers, most of them psychologists with psychiatric experience, have been extensively trained by experts in the field, and data assurance measures will stay implemented throughout the study.

Findings from the MEMENTA-Study will fill a fundamental lack of knowledge, add important information to be used by practitioners and politicians and, hopefully, stimulate further research into the development of an appropriate mental healthcare system for people with ID and mental illness.

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Contributors MS is responsible for the conception of the project and wrote the research proposal. AK and AV drafted this manuscript based on the research proposal and on contributions to the design of the study by all other authors. MH, AP, HJS and BP revised the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

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Competing interests None.

Patient consent Obtained.

Ethics approval Approval of all three local ethics committees was obtained (Carl Gustav Carus University Hospital; Technische Universität Dresden; Central Institute of Mental Health, Mannheim; Ulm University, Günzburg).

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MEMENTA—'Mental healthcare provision for adults with intellectual disability and a mental disorder'. A cross-sectional epidemiological multisite study assessing prevalence of psychiatric symptomatology, needs for care and quality of healthcare provision for adults with intellectual disability in Germany: a study protocol

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