

Title

Case management and care expertise as a prevention approach for adults with intellectual disabilities: results of a randomized-controlled trial

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Credit Roles

Stephan Nadolny: Validation, formal analysis, investigation, data curation, writing - original draft, visualization, supervision, project administration. **Marie Grunwald:** Formal analysis, investigation, data curation, writing – review & editing, visualization. **Annika Gröndahl:** Formal analysis, investigation, data curation, writing – review & editing, visualization. **Sarah Palmdorf:** Investigation, writing – review & editing. **Karina Iliskens:** Investigation, writing – review & editing. **Nina Borchardt:** Investigation, writing – review & editing. **Annika Maaß:** Investigation, writing – review & editing. **Tessa Schlenker:** Writing – review & editing. **Stefanie Schniering:** Writing – review & editing, project administration. **Dariusch Afroukhte:** Investigation, writing – review & editing, project administration. **Miriam Tariba Richter:** Conceptualization, resources, writing – review & editing, supervision, project administration, funding acquisition. **Matthias Offermanns:** Writing – review & editing. **Ann-Kathrin Parloh:** Writing – review & editing. **Christian Grebe:** Conceptualization, formal analysis, methodology, writing – review & editing, supervision, project administration, funding acquisition. **Änne-Dörte Latteck:** Conceptualization, resources, writing – review & editing, supervision, project administration, funding acquisition.

Abstract

Background: People with intellectual disabilities have a higher prevalence of certain chronic diseases and higher avoidable mortality. Some of these diseases or their exacerbation could be avoided through disease prevention and health promotion interventions, as people with intellectual disabilities have high rates of unhealthy eating habits, stress, lower levels of mobility and similar addictive behaviours to the general population. At the same time, they face significant barriers to accessing preventive healthcare interventions.

Objective: To test the effectiveness of an advanced practice nurse-led case management and prevention intervention for people with intellectual disabilities on health status after 12 months.

Design: Two-arm parallel randomised-controlled trial with waiting list.

Setting(s): Community setting in an urban area of Hamburg, Germany.

Participants: 214 adults with an ICD-10 diagnosis F70-79 and a care level below 4 according to German Social Code XI, who were not at the end-of-life.

Methods: The intervention consisted of case management, social space analysis, prevention planning and counselling in four outreach home visits on the topics of addiction, mobility, nutrition and stress. The control group received usual care. Participants were allocated using permuted block randomisation. The primary outcome was health status (WHODAS, 0-100) at 12 months (t2). Secondary outcomes were health status at 6 months (t1), resilience (RS-11, 7-77) and health-related quality of life (EQ5D, 0-100) at t1 and t2. Lower scores indicate better health status and higher scores better resilience and quality of life. Raters and analysts were blinded. Analyses were performed with ANCOVAs and Bonferroni correction to $\alpha = 0.025$ and 97.5% confidence intervals (CI).

Results: We randomised 107 participants to each group. For the primary outcome health status at t2 ($n=167$), the mean difference (MD) was -4.38 (CI: -8.13 to -0.62, $\hat{\eta}^2 = 0.041$). For the secondary outcome of health status at t1, the MD was -1.06 (CI: -3.51 to 5.62, $\hat{\eta}^2 = 0.002$). For resilience, the MD was +0.51 (CI: -3.11 to 2.10, $\hat{\eta}^2 = 0.001$) at t1 and +2.70 (CI: -5.78 to 0.39, $\hat{\eta}^2 = 0.022$) at t2. For health-related quality of life, a MD of +0.72 (CI: -5.88 to 7.32, $\hat{\eta}^2 = 0.000$) at t1 and -1.19 (CI: -8.71 to 6.33, $\hat{\eta}^2 = 0.001$) at t2 were measured.

Conclusions: Overall, a nurse-led intervention focusing on prevention and case management can lead to a statistically significant change in health after 12 months, but not for the secondary outcomes. The current literature on minimal clinically important differences indicates that the effect is also clinically important.

Registration: German Clinical Trials Register DRKS00028771, registration 4 July 2022, first recruitment 1 September 2022

Social media abstract: *Nurse-led intervention focused on prevention for people with intellectual disabilities leads to improvement in health status after 12 months*

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Keywords

Advanced practice nursing; clinical trial; Germany; health promotion; intellectual disability; learning disabilities; nursing; persons with intellectual disabilities; prevention; randomized controlled trial;

What is already known

- People with intellectual disabilities have a higher prevalence of certain chronic diseases, disability and avoidable mortality.
- People with intellectual disabilities face several barriers, both (inter-) personal and systemic, when accessing healthcare services.
- There is a substantial need for tailored, low-threshold prevention and health promotion interventions for the target group.

What this paper adds

- A complex intervention combining case management and care expertise can lead to a clinically important difference in the health of people with intellectual disabilities after 12 months.
- Improvements in health status were observed after 12 months but not after six months, highlighting the importance of longer follow-up periods when evaluating complex prevention and case management interventions.
- The findings support the feasibility of a nurse-led, outreach prevention and case management approach for adults with intellectual disabilities in a community setting.

Background

It is estimated that approximately one to two percent of the general population have an intellectual disability [1, 2].

People with intellectual disabilities are at an increased risk of developing chronic diseases such as epilepsy, obesity and diabetes [3–5] with a higher avoidable mortality [6–8]. Potential risk factors include that people with intellectual disabilities are more likely to have unhealthy eating habits [9], sedentary behaviour [10] and low levels of physical activity [11, 12]. Furthermore, individuals with intellectual disabilities frequently experience elevated levels of stress [13], stress-related disorders [14], and have comparable or even higher rates of substance use [15, 16] as well as addictive behaviours such as gaming [17] or internet use [18].

At the same time, individuals with intellectual disabilities encounter difficulties in accessing and managing healthcare interventions effectively, due to a number of barriers. These include the use of different communication needs/strategies [19, 20], a lack of appropriate information [21], a shortage of professionals with the requisite skills to work with people with intellectual disabilities [22–24], a lack of tailored interventions [25] and similar to lower levels of health literacy than the general population [21].

In light of the evidence indicating an increased risk of developing certain diseases and engaging in unhealthy behaviours, which are associated with an increased mortality rate, it is clear that individuals with intellectual disabilities require targeted prevention and health promotion interventions. However, despite the fact that they are entitled to equal access to healthcare under the United Nations Convention on the Rights of Persons with Disabilities [26], they face significant barriers to accessing these interventions.

Consequently, a case management support system with healthcare professionals may be a viable approach. Quantitative evidence on case management is limited [27–30], as the impact on health may be moderated by other contextual factors [31]. Nevertheless, case management may have positive effects on self-care and self-management, and on communication between health professionals, clients and their caregivers [28]. Qualitative studies have demonstrated a number of effects, including improved access to healthcare through coordination and advocacy, continuity of care, and improved health literacy [32, 33]. However, there is a paucity of evidence on the effectiveness of case management for people with intellectual disabilities, with only very few studies exploring the topic [34, 35].

The evidence base for health promotion interventions tailored to people with intellectual disabilities is broader, although it remains limited. A number of reviews have been conducted on the topic, with the largest body of evidence emerging for weight management and lifestyle changes [3, 36].

Nurses, and in particular advanced practice nurses, possess specialised expertise in diagnosing (potential) health risks and individual influencing factors and in initiating appropriate interventions by referring participants to suitable interventions or providing these interventions themselves.

The role of advanced practice nurses has been interpreted and implemented differently internationally [37–39].

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Nurse-led interventions have shown to be promising for people with intellectual disabilities [40, 41] for prevention and health promotion [42, 43]. Indeed, a number of models and theories have been developed for nursing practice with this population [44–47]. However, the role of advanced practice nurses in this area has not been widely implemented, with the exception of Ireland [48, 49]. This is also true for Germany [50]. Nevertheless, the implementation of advanced nursing practice and clinical nurse specialist approaches has proven feasible and effective for other groups with complex care needs [51–53].

Therefore, the goal of this study was to test the effectiveness of an advanced practice nurse-led case management and prevention intervention on health status for people with intellectual disabilities.

There are cultural differences in the way this target population is labelled, with the most common descriptions being people with intellectual disabilities or people with learning disabilities. In Germany, interest groups have called for the description to be changed to people with learning difficulties. In accordance with the formal project title and the descriptions employed in the German Social Code, we will use the term 'people with intellectual disabilities' throughout this article.

Methods

Trial design

A randomised-controlled trial with a parallel group and waiting list design was conducted from October 2022 to January 2024 with an allocation ratio of 1:1.

Participants

The study's target group comprised people with intellectual disabilities residing in all seven districts of Hamburg, Germany. To be eligible for inclusion, participants were required to meet the following criteria: an ICD-10 diagnosis of F70 to F79 and a minimum age of 18 years. Those who met the following exclusion criteria were not eligible for participation: being at the end of life or having received a care level greater than three of five according to the German Social Code XI [54]. This relates to a severe impairment of independence or abilities, with at least five hours of nursing care needed per day.

Recruitment

Recruitment was performed by 1) [institution blinded] via the advanced practice nurses who delivered the study's intervention and 2) researchers from the [institution blinded], who had no contact with the data collection and analysis of the randomized-controlled trial, 3) two health insurance funds that were part of the research consortium.

For recruitment routes 1 and 2, the cooperation partners in ambulatory and residential integration assistance that had provided letters of intent beforehand were contacted. Information events with the possibility to ask questions or talk

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directly to the nurses and researchers were held in the residential institutions or ambulatory integration assistance offices with open invitations for potential participants. In 3) postal mailings were sent to potential participants with the invitation to participate in the study.

In general, there was a contact telephone number and email address established at the [institution blinded] for individual inquiries about the study.

Recruitment started in July 2022, with the first participants being enrolled in September 2022 and concluding in December 2022. The study commenced with two cohorts in October 2022 and January 2023.

Intervention

Our intention was to employ master's-level nurses who would act as case managers and use their advanced nursing skills. However, due to the small number of advanced practice nurses available in Germany, it was very difficult to fill all positions with this profile. For this reason, two of the ten positions were filled by other master's-level health professionals, who had extensive experience in the field of prevention and health promotion. These case managers are working at the [blinded]. Their role involved performing key tasks in case management such as gatekeeping, brokering, and advocacy. The intervention's main focus was disease prevention and health promotion for people with intellectual disabilities. It focuses on four specific areas of prevention, as outlined in the legal guidelines for prevention in Germany [55, 56]. These include: 1) nutrition, 2) mobility, 3) stress and 4) addiction.

The intervention consisted of four home visits conducted over the course of one year. Prior to the visits, a social space analysis [57] was conducted for each of the seven Hamburg districts. This entailed mapping out the existing service structure and identifying gaps or accumulations. This served as a starting point for networking with the service providers and as an orientation point for referring the participants to suitable service providers with regard to the brokering and gatekeeping element of case management. Additionally, the analysis indicated the need to conceptualise further consultation interventions, needed to be provided by the advanced practice nurses themselves. For each district one to two nurses or health experts were employed, depending on the size of the target population in the respective district. The consultation interventions were carried out both individually and in groups.

The initial home visits were designed to facilitate the establishment of a professional relationship between the participants, their caregivers, and the nurses and health experts. Additionally, they served to conduct a preliminary screening of existing and potential health problems and resources, as well as individual motivation. Biographic interviews were employed to explore pertinent contextual information [58]. The language level was tailored to align with the client's abilities, ranging from basic to advanced language, including Easy Language. The Easy Language rules of the German Easy Language Network were used [59]. Additionally, the participants and advanced practice nurses agreed on rules of cooperation.

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The second visit also occurred within the first month and comprised a comprehensive assessment of health problems based on the InterRAI intellectual disability assessment [60]. A network map was created to illustrate the social network of the participants. Further differentiated assessments were carried out on a case-by-case basis, depending on which domain of prevention was considered relevant.

The third visit took place in the second month and aimed to develop a participatory prevention plan. The plan was developed through the formulation of individual goals, (potential) health problems and resources, preventive interventions, and actions to improve health, as well as suitable outcomes for evaluation. These elements were based on the aforementioned assessments. The plan was developed in collaboration between the client, the primary caregivers, and additional professionals. Primary caregivers were nominated by the participants. They were people with knowledge about the participants' health, abilities and general situation. They were professionals, family members or friends. These first three visits were each carried out jointly by a team of two nurses or health experts, at least one of whom was an advanced practice nurse. The fourth visit occurred after one year and served for the evaluation of the prevention plan. Moreover, overarching goals for the client's health beyond the project were defined in collaboration with the client and their caregivers in order to ensure continuity.

In between the home visits, the nurses and health experts held liaison with the participants in person, and through various communication channels, including telephone, email, digital messages and video conference. Every two months, the prevention plan was reviewed and updated as necessary. Given that people with intellectual disabilities frequently encounter difficulties in enrolling in healthcare programmes [19], the nurses and health experts assumed the roles of brokers and advocates, facilitating their enrolment in and utilization of the required care or interventions. Additionally, they performed gatekeeping functions with regard to certain interventions, if those interventions were not primarily indicated. They conducted single-person interventions through counselling regarding the four areas of prevention, if no suitable services were available. This included, for example, counselling on stress reduction in the absence of suitable interventions, as well as referring participants to other existing services, for instance, numerous activities already existed for physical activity. Referral also kept the nurses' workload manageable.

The nurses and health experts documented their work in a standardised documentation system developed for this study.

The control group received usual care. Since prevention and health promotion are not well covered by the existing practice, we opted not to offer an active intervention. The nurses and health experts would not approach individuals from the control group. However, given that they were situated in the offices open to the public in the community, it could not be avoided that control patients could receive advice or counselling on healthcare problems. Nevertheless, no reports were received indicating that this had occurred.

To enhance adherence to the intervention, comprehensive intervention descriptions were developed for each home visit. However, due to the

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communicative, educational, and coordinating nature of this complex intervention, a degree of flexibility was essential to tailor the intervention to the diverse needs of individuals in this population.

Given that advanced practice nursing is not widely available and is concentrated in a limited number of centres in Germany, the nurses had varying qualifications (see table 1):

They received 80 hours of formal training with accompanying digital materials and self-study units on the following topics:

- Social space orientation [61] and social space analysis
- People with intellectual disabilities as a target group
- Communication with people with intellectual disabilities
- Care for people with intellectual disabilities
- Prevention and health promotion for people with intellectual disabilities
- Legal framework
- InterRAI intellectual disability assessment

Data collection

Data collection was conducted at three time points: baseline (t0), six months (t1) and twelve months (t2). Data were gathered through structured face-to-face interviews conducted in the participants' preferred location (e.g. home, work, etc.) in conjunction with the primary caregiver. In exceptional cases, data were collected via telephone (e.g. if the participant was on vacation). The raters underwent training in quantitative data collection, standardised interviewing with people with intellectual disabilities and Easy Language. Each item was read verbatim as stated in the outcome measures. Explanations in an easier language for the specific questions in the self-reported outcome measures were developed to provide participants with additional support during data collection, if necessary. A pre-test was conducted, which led to the restructuring of the order of the outcome measures. The previous version of the questionnaire started with the resilience assessment; however, this was subsequently amended to commence with the health-related quality of life assessment.

In addition to the outcome measures, data were collected on age, sex, district of Hamburg, living situation and daily support. Living situation was further subdivided into ambulatory and residential settings. In Germany, a residential setting is defined as having a professional carer present 24 hours a day. This may be comparable to a nursing home or a shared apartment with permanent care, depending on the needs. The outpatient setting referred to a living arrangement in which people did not live with their family or on their own. They received professional care for part of the day. This was usually organised in shared or individual flats with a professional's office nearby.

Outcomes

The primary outcome of the study was the health status after twelve months (t2) as measured by the 32-item World Health Organization Disability Assessment Schedule (WHODAS 2.0, interviewer version) [62]. The WHODAS

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comprises six domains: cognition, mobility, self-care, getting along, life activities and participation.

The WHODAS has been validated with numerous studies and shows good validity and reliability in several populations and settings [63]. Overall internal consistency ranges from Cronbach's alpha from 0.84 to 0.98 and test-retest reliability from intra-class correlation coefficient 0.80 [63] to 0.98 [62].

Data for the primary outcome was collected in a proxy assessment with the primary professional or formal caregivers. Secondary outcomes were:

1. Health status after six months (t1) measured with the WHODAS (proxy assessment),
2. Resilience after six (t1) and twelve (t2) months measured with the Resilience Scale 11 (RS-11) [64] (self-assessment),
3. Health-related quality of life after six (t1) and twelve (t2) months measured with the EuroQol EQ5D VAS [65] (proxy and self-assessment)

We used the German versions of all outcome measures.

To provide further illustration of the clinical characteristics of the population, the WHODAS domains of cognition, mobility, self-care, getting along, life activities and participation were reported at baseline.

Sample Size

A power analysis was conducted using the software G*Power [66] to determine the required sample size for the study. Given the innovative nature of this care model, particularly with regard to its complexity and target population, it was not possible to use effect sizes from closely comparable studies a priori. Similar complex interventions involving case management predominantly show moderate to weak effects.

We therefore took a pragmatic approach to sample size estimation, assuming a moderate effect size based on an effect size of $f = 0.23$ (a moderate effect assuming that 5% of the variance would be explained by the group effect), as determined by ANCOVA.

Based on an effect size of $f = 0.23$ for an ANCOVA, a power of 0.8, and a significance level of 0.05 with Bonferroni correction to 0.025, the analysis indicated that 184 participants were needed to achieve sufficient statistical power. A 30% dropout rate was estimated due to the one-year time frame, the specifics of the target population, and the complex nature of the intervention. Therefore, it was planned to recruit 256 participants (128 per group) into the study.

Randomisation

The participants were randomized with the R package randomizeR [67] with randomly permuted blocks of two, four or six [68].

The random allocation sequence was generated by a researcher [blinded] responsible for making the appointments for data collection with the

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participants. The individual at [blinded] responsible for generating the allocation sequence was also responsible for assigning participants to groups and informing the coordinator of the advanced practice nurses of which participants were in which group.

Blinding

Due to the nature of the intervention, it was not possible to blind participants and advanced practice nurses. However, blinding was possible for raters and analysts. The blinding status of the raters was assessed at each time point. We instructed the participants and their primary caregivers to refrain from disclosing their group allocation. Additionally, raters were advised to avoid discussing the intervention themselves or encouraging participants to do so. The data were analysed by several analysts ([blinded]), each of whom was blinded to the other analysts' findings, in order to ensure the minimisation of bias in the analysis process. Once the analysis was complete, the group allocation was revealed.

Analysis

The data were transferred from the paper-based questionnaires to a pre-specified digital matrix by two raters [blinded] simultaneously at each stage. We developed a codebook of variables and values to ensure data quality. The data were checked for double entries, missing and ineligible values by the project lead of the randomized controlled trial [blinded].

For the outcome measures RS-11 and WHODAS, missing values were imputed using simple case-wise imputation. With regard to RS-11, the number of missing values was minimal, with only five participants having one item missing. Therefore, the mean of the remaining items for each case was imputed. With regard to WHODAS, the guideline in the handbook was followed, as the number of missing values was always below two missings [62]. The mean score across all items for the respective WHODAS domain was imputed case-wise. Individuals with complete absence of data for the outcome measures were excluded from the analysis. We did not impute data on the EQ5D.

To ascertain baseline differences, we employed Chi-square tests and Fisher's exact test for nominal variables with cells with $n < 10$, and independent t-tests for metric variables at a two-sided significance level of 0.05.

We performed ANCOVAs with each outcome separately at the respective time point (t1, t2) as the dependent variable and the baseline value (t0) serving as the covariate to test for group differences. Three hypotheses were tested at a Bonferroni-adjusted significance level of 0.025 each. The alternative hypotheses were as follows: The intervention group differed from the control group in: 1) the health status after six and twelve months, 2) resilience after six and twelve months and 3) health-related quality of life after six and twelve months.

The following assumptions were tested for each ANCOVA: 1) homogeneity of regression slopes with exploration of interaction effects, 2) linearity between

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covariate and independent variable with linearity test, 3) normal distribution of standardised residuals with Shapiro-Wilk and Kolmogorov-Smirnov tests as well as the inspection of Q-Q Plots, 4) homoscedasticity using Levene's test, and 5) outliers and extreme values with leverage values and Cook's distance values. The leverage values were analysed using the threshold proposed by Igo [69], while Cook's distance values were assessed using a value of 1.0 as a threshold [70]. In the event of non-normality, we performed bootstrapped ANCOVAs with 1000 samples and the bias-corrected and accelerated method [71].

A comparative analysis was conducted between dropouts and remaining participants, with the aim of identifying any potential differences in outcomes. Additionally, a comparison was made between the dropouts in the intervention and control group to ascertain any relevant distinctions.

Since the intervention was planned as an advanced-nursing practice intervention, we performed a sensitivity analysis with an ANCOVA for the participants who were treated by nurses only as the analytic filter.

The data will be reported in absolute and relative frequencies as well as mean and standard deviation (SD). Additionally, differences between groups will be presented as covariate-adjusted mean differences (MD) for the ANCOVA with its corresponding confidence intervals (CI). For baseline differences, 95% confidence intervals will be reported and 97.5% confidence intervals for the ANCOVA to take Bonferroni correction to a significance level of 0.025 into account. The magnitude of the effect will be illustrated with partial eta-squared. The models will be reported with F-Statistics, degrees of freedom and adjusted R^2 for goodness of fit.

We used intention-to-treat analysis for participants who had dropped out of the intervention.

The data analysis was performed with IBM SPSS Version 29.0 [72].

Ethical approval

Ethical approval was granted by the [blinded] ethics commission (No. 2022–10, 21 June 2022). The study participants and, if applicable, their legal guardians were informed verbally and in writing by the nurses and health experts. Written informed consent was obtained from the study participants and, if applicable, their legal guardians by the advanced practice nurses. Ongoing consent could be revoked at any point during the study period, up until the final day of data collection, because contact details and clear names on the reference lists were deleted subsequently.

Registration

The study has been registered in the German Clinical Trials Register: DRKS00028771 on 4 July 2022 (Universal Trial Number: U1111-1277–0595). The first participant was recruited on 1 September 2022. The study protocol has been published (Nadolny et al., 2023).

Results

We recruited 214 people with intellectual disabilities into the study. Further illustration of the flow of participants can be seen in the CONSORT flow chart (see figure 1). The cumulative dropout rate was 4.21% at t0, 12.2% at t1 and 17.3% at t2. The reasons for dropout were as follows: lost motivation (n= 7), no more time for participation (n= 7), lost interest (n= 6), lost contact (n= 5), too many dates for intervention and data collection (n= 3), no further need for intervention (n= 2), too stressful (n= 2), took alternative intervention (n= 1), moved away from Hamburg (n= 1), intervention and data collection are not helpful (n= 1), intervention too physically demanding (n= 1) and incorrect study inclusion (n= 1). The individual who was erroneously included in the study had a care level greater than three and was subsequently excluded from the study during t0 data collection.

Furthermore, seven proxy non-responders did not answer the WHODAS and EQ5D assessment at t2, resulting in 167 analysable cases for the primary outcome at t2.

Baseline characteristics between groups were similar (see table 2).

In terms of outcomes, we found a statistically significant baseline difference in the health-related quality of life proxy assessment with a mean of +6.05 in favour of the intervention group ($p= 0.017$). Participants exhibited higher levels of disability in all domains of the WHODAS, with the greatest problems in the domain of life activities, participation and getting along.

ANCOVA

The results of the ANCOVA are presented in table 3. Detailed model results for each ANCOVA are displayed in supplement 1.

All outcomes are reported as covariate-adjusted MDs with the intervention group serving as the reference. Higher scores on the health status indicate worse health, whereas higher scores on resilience and health-related quality of life instruments indicate better resilience and quality of life.

With respect to the primary outcome, health status at t2, a group effect was identified with a MD of -4.38 ($F(1,164)= 0.272$, $p= 0.009$, $CI= -8.13$ to -0.62 , adjusted $R^2= 0.449$).

With regard to the secondary outcomes, we identified no group effects.

However, the results of the ANCOVAs are as follows: the health status at t1 reached a MD of -1.06 ($F(1,181)= 0.272$, $p= 0.602$, $CI= -3.51$ to 5.62 , adjusted $R^2= 0.234$).

The resilience score at t1 demonstrated a MD of +0.51 ($F(1,181)= 0.184$, $p=0.660$, $CI: -3.11$ to 2.10 , adjusted $R^2= 0.339$) and a MD of +2.70 at t2 ($F(1,170)= 3.904$, $p= 0.050$, $CI= -5.78$ to 0.39 , adjusted $R^2= 0.318$).

The health-related quality of life (self-assessment) was found to have increased by a MD of +0.72 ($F(1,182)= 0.061$, $p= 0.000$, $CI= -5.88$ to 7.32 , adjusted $R^2= 0.260$) at t1 in favour of the intervention group and a MD -1.19 ($F(1,181)= 0.129$, $p= 0.720$, $CI= -8.71$ to 6.33 , adjusted $R^2= 0.720$) at t2 in favour of the control group.

The proxy assessment of health-related quality of life yielded a MD at t1 of -0.91 ($F(1,179)= 0.131$, $p=0.718$, $CI= -6.63$ to 4.80 , adjusted $R^2= 0.270$) in favour

of the control group and a MD of +0.78 ($F(1,163)= 0.089$, $p= 0.766$, $CI= -5.17$ to 6.73, adjusted $R^2= 0.263$) in favour of the intervention group at t2.

ANCOVA assumptions

We tested assumptions for all ANCOVAs. Homogeneity of regression slopes was not violated with regard to the dependent variable, as the interactions were not statistically significant ($p> 0.05$). Linearity of the covariate and independent variable were analysed using linearity tests and all tests returned statistically insignificant results ($p> 0.05$). The assumption of homoscedasticity was tested with Levene's test, and it was found that equality of variances was met for all ANCOVAs ($p> 0.05$).

The presence of outliers was evaluated through the application of Cook's distance and leverage values. No values for Cook's distance exceeded the critical value of 1. For leverage values, only few relevant outliers were identified. Nonetheless, we performed ANCOVAs with the exclusion of outliers, and the direction of effects remained stable.

Standardized residuals were analysed for normal distribution for all outcomes with Shapiro-Wilk as well as Kolmogorov-Smirnov test. The assumption of normality was violated in the WHODAS at t2 (Kolmogorov-Smirnov: $p= 0.046$, Shapiro-Wilk: $p= 0.04$), EQ5D self-assessment at t2 (Kolmogorov-Smirnov: $p= 0.093$, Shapiro-Wilk: $p< 0.001$) and EQ5D proxy at t1 (Kolmogorov-Smirnov: $p= 0.014$, Shapiro-Wilk: $p< 0.001$) and t2 (Kolmogorov-Smirnov: $p= 0.093$, Shapiro-Wilk: $p< 0.001$). Q-Q Plots showed also indicated of non-normality. Therefore, we performed bootstrapped ANCOVAs for those outcomes, but the results remained robust (see bootstrapped pairwise comparisons in supplement 2).

Dropout analysis

We analysed the data for people who dropped out of the study and for whom data were available ($n= 28$). The dropouts were in mean of younger age (36.07 ± 11.2 years). They were predominantly male ($n= 16$, 57.1%) and 50.0% ($n= 14$) resided in the ambulatory setting.

A comparison of the dropouts with the remaining participants regarding the outcome data revealed that the dropouts exhibited higher scores on the EQ5D at all time points, lower scores on the RS-11, and higher scores on the WHODAS (see supplement 3). However, these differences were not statistically significant.

Comparing the differences between the intervention group and control group, the intervention group ($n= 17$) lost participants who had higher scores on the WHODAS over all time points. The MD in scores were +9.57 (95% $CI= -20.55$ to 1.40) at t0 and +4.62 (95% $CI= -43.72$ to 34.48) at t1.

Additionally, they exhibited lower scores on the RS-11 at t0 +3.05 (95% $CI= -6.15$ to 12.25) and at -0.63 (95% $CI= -19.88$ to 18.63) at t1. Furthermore, in the EQ5D self-report showed lower scores at both time points, with a MD at t0 of -0.63 (95% $CI= -18.16$ to 16.90) and -11.67 (95% $CI= -45.21$ to 21.87) at t1. The same trend was present for the EQ5D proxy assessment at t0 -15.52 (95% $CI= -31.12$ to 0.09) and -7.08 (t1) (95% $CI= -49.19$ to 35.03).

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To address the potential impact of the dropouts, we imputed the dropouts' missing outcome data for all outcomes using the values of the last available data point and repeated the ANCOVA for all outcomes. The results remained robust. The effect of the intervention on WHODAS at t2 remained statistically significant, although the magnitude was reduced. The covariate-adjusted mean difference was of -3.79 in favour of the intervention group ($F(1,192)= 6.01$, $p= 0.015$, 97,5% CI= -7.29 to -0.30, adjusted $R^2= 0.481$, $\eta^2= 0.030$). All other outcomes remained not statistically significant.

We performed a post-hoc power analysis with G*power and identified that our study had a power of 0.76 to find the intended difference of $f= 0.23$ in the primary outcome.

Sensitivity analysis

Due to the fact that we initially intended the intervention to be an advanced practice nurse-led intervention, we performed sensitivity analyses restricted to participants cared for by advanced practice nurses only for all outcomes with stable results. The results for the WHODAS at t2 were: ($F(1,134)= 5.37$, $p= 0.022$, 97,5% CI= -9.46 to -0.10, adjusted $R^2= 0.425$, $\eta^2= 0.039$). (see supplement 4)

Blinding of raters

At t0, group allocation had been revealed to raters in 18.4% ($n=27$), while at t1 it was 36.0% ($n= 67$) and at t2 40.3% ($n= 71$). In the majority of cases, participants informed the rater (65.7%; $n= 115/175$ data collections where unblinding occurred).

Discussion

We conducted a randomised-controlled trial on the effectiveness of a nurse-led case management and prevention intervention for people with intellectual disabilities. To the best of our knowledge, this is the first study on advanced nursing practice and prevention in Germany. We observed an effect on health status after twelve months. However, we did not find positive results on the health status after six months, nor on resilience or on health-related quality of life after six and twelve months.

A total of 17.3% of participants dropped out of the study, which was lower than the initially anticipated rate of 30%.

There were no concerning reasons for dropouts, but participants had numerous appointments during the study, including at least four home visits, possible prevention or health promotion interventions, and three data collection visits over the course of a year. This may be challenging for participants in any population to integrate into their daily lives. In particular, people in the control group lost interest over time. This is understandable, as the participants were eager to become involved in prevention immediately. Discussions with the participants revealed that the lengthy waiting period of one year before the

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waiting list intervention commenced and the necessity for data collection still proved too much for some participants. It is noteworthy that particularly younger individuals dropped out of the study, and those in the intervention group with a lower health status, resilience, and quality of life. These individuals may have benefited from the intervention to a greater extent than others. However, dropout analyses showed that the effect on health status after twelve months remained statistically significant, although the magnitude of the effect was slightly reduced.

It is notable that the data on the outcomes at t1 showed only minor variations from baseline. One possible explanation is that the intervention required time to become effective. The first months focused on assessment, relationship-building, the development of a participatory prevention plan and facilitating access to suitable prevention or health promotion services. Therefore, measurable changes in health status may only become apparent after a longer implementation period. Further reasons will be explored in the ongoing process evaluation.

Clinical relevance of the results

The results of this study showed a positive and statistically significant effect of a nurse and health experts-led case management and prevention programme on health status after twelve months only. Additionally, the effect on resilience after twelve months was not statistically significant, although the confidence intervals indicate that the lack of statistical significance may reflect either the absence of a relevant effect or insufficient statistical power.

The health status of the intervention group improved by an average of 4.38 points. However, it is uncertain whether this difference represents a clinically significant outcome. Since there are no similar studies in people with intellectual disabilities, we compared our results with studies in other populations. In an intensive care population a change of 10% [73] and in a study in surgical patients, a change of 5% [74] were considered clinically important. In patients with musculoskeletal pain, a change ranging from 3.1 to 4.3 [75], was considered important, as was a change of 3.22 to 5.99 points in patients with back pain [76] and a change of 3.5 points in patients with traumatic brain injury [77]. The mean change from baseline in our study was an improvement of 12.2%. In light of the findings of previous studies on the minimal important difference, we believe that our results indicate a clinically important effect. Nevertheless, research on the minimal clinically important difference in relation to the WHODAS assessment remains limited and target-group-specific thresholds for people with intellectual disabilities are needed [63, 78].

Intervention - qualification of advanced nurse practitioners

The intervention was planned as an advanced practice nursing intervention. However, the practice partner was unable to employ nurses at the master's level throughout the entire study. Two nurses who replaced advanced practice nurses who had left the project had only a bachelor's degree and were in the process of completing a master's degree, and two health experts had no nursing degree.

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This reflects the limited availability of academically qualified nurses in Germany. Although the German Council of Science and Humanities recommended that 10% to 20% of nurses should hold an academic degree [79], only about 3.2% of nurses have an academic degree % [80] and only 2.1% work in direct patient care [81]. Structural barriers include limited recognition of academic nursing degrees, few clinical career pathways, and the delayed academisation of nursing in Germany. Advanced nursing practice master's programmes remain rare [82, 83], although their number has increased in recent years [84]. In addition, nurses in advanced practice roles in Germany do not always have formal qualifications or tasks aligned with their role [85], and they lack the legal authority to prescribe medical aids or prevention courses [86, 87]. Nevertheless, initial steps have been taken in the political discourse to address this situation, particularly in the context of dementia care, diabetes care and wound care.

Therefore, the intervention should be interpreted as a nurse-led, interprofessional case management and prevention intervention rather than as a purely advanced practice nursing intervention. This has implications for transferability, as future implementation may require both advanced nursing competencies and collaboration with other professionals with expertise in prevention and health promotion.

Intervention transferability - the care system in Germany

The German care system for people with intellectual disabilities presents a significant challenge from a professional and case management perspective. This is due to the involvement of numerous professions as well as the different funding sources for care outlined in the German Social Code [88]. These include professionals from social pedagogy, social work, social care work, as well as personal assistants, who are funded by the German Social Code to ensure participation. Nurses are rarely involved in the care of people with intellectual disabilities with the exception of those requiring aged long-term care [89, 90]. This is due to the system's focus on participation rather than healthcare. Consequently, general practitioners, neurologists and dentists are often the primary healthcare professionals in contact with people with intellectual disabilities. The lack of healthcare professionals monitoring potential health problems, particularly in the context of the increased risk of chronic diseases and avoidable mortality, is a significant concern. We argue that a combination of professions is required for specific tasks. However, it is important to consider the difficulties in accessing healthcare and potentially negative previous experiences [20, 91]. Nurses, particularly advanced practice nurses, may be well suited to navigate and support individuals with intellectual disabilities in relation to prevention and health promotion, as well as to improve health literacy [48, 49]. This responsibility should not be borne by professionals whose primary focus is on social dimensions. Moreover, health is a fundamental prerequisite for participation.

The intervention was conducted in the urban area of Hamburg, a city with a population of 1.8 million. Urban areas typically offer a multitude of prevention and health promotion services, which makes the intervention suitable for transfer to other urban areas. However, to transfer the intervention to rural

areas, adaptations may be necessary, as brokering participants into existing services may be more challenging.

Distribution of outcome data at baseline

There are only few studies on the health-related characteristics of people with intellectual disabilities in Germany. Consequently, we compared our data with population norms and validation studies. The overall mean WHODAS score for our study participants was 35.70. When compared to population norms in the WHODAS handbook [62], the participants in the study were found to be in the upper 10th percentile of the general population. The baseline results of our study are comparable with a smaller study on people with autism, which scored a mean of 35.92 [92] and higher than a study on people with disabilities (17.97) [93].

This indicates that our population had considerably higher disability than the general population as well as the sub-population of people with disabilities. Regarding resilience, we compared our results with two studies using the same assessment from Germany. The mean score in our study was 54.13, while in the respective studies individuals scored 58.03 [64] and 59.61 [94]. The observed difference appears to be minor, but when viewed in the context of the general population, our participants are close to the lower quartile [94] or lowest 35% [64]. This suggests that people with intellectual disabilities may exhibit lower levels of resilience than the general population.

The mean health-related quality of life score for our participants was 66.68, which is lower than the scores reported in two German studies in the general population. The scores in these studies were 71.6 [95] and 85.1 [96], respectively. This suggests that people with intellectual disabilities may have lower health-related quality of life than the general population.

Although our study is not a representative cross-sectional study, the baseline results of our sample are cause for concern. They indicate that people with intellectual disabilities may have a decreased health status, resilience and quality of life compared to the general population. This is a call to action for researchers and practitioners alike. In order to obtain more robust data, it is necessary to survey the population representatively. Furthermore, in practice, interventions should specifically address these areas.

Limitations

The intended sample size of 256 participants, which included an anticipated 30% dropout rate, was not reached due to recruitment difficulties. A total of 214 participants were recruited. Calculations indicated that 186 participants were required at t2 to identify a statistically significant effect of $f = 0.23$ for the primary outcome. Although the dropout rate was much lower than expected, we reached a sample size of only 167 participants for the primary outcome at t2. The insufficient number of cases resulted in a post-hoc power of only 0.76 to detect the intended effect size. Nevertheless, we found statistically significant and clinically important differences for the primary outcome. However, the

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97.5% confidence interval was relatively wide, suggesting some degree of imprecision.

Baseline differences in health-related quality of life were statistically significant, but since the ANCOVA takes baseline values into account, this did not influence the results negatively.

The results for resilience did not reach statistical significance. Given that a difference of four to five points at the population level may correspond to being in the mean or being in the lower quartile, a much bigger sample size may have been required to show an effect.

As the study excluded people with intellectual disabilities and a care level of three or higher, the findings cannot be generalized to people with a greater need for care.

A further limitation relates to the composition and previous experience of the intervention team. Although the intervention was nurse-led and the first three home visits were conducted in tandems including at least one advanced practice nurse, not all professionals delivering the intervention were nurses. In addition, most members of the intervention team had limited prior experience with people with intellectual disabilities. However, structured training, standardised intervention descriptions and tandem delivery were used to reduce variation in implementation. Moreover, the sensitivity analysis restricted to participants cared for by nurses showed stable results.

A high rate of unblinding of outcome assessments was observed, reaching over 40% at t2. This was anticipated, because although people with intellectual disabilities might understand the need for blinding, three data collection sessions over the course of a year posed a significant challenge for the target group to remember the importance of blinding. Frequent reminders were provided to participants regarding the importance of maintaining confidentiality of the group allocation, yet this was not consistently upheld. Efforts were made to ensure that raters did not visit the same individuals on more than one occasion for data collection. However, this was not always feasible due to travel times in Hamburg, last-minute cancellations and the rescheduling of appointments. In addition, the data were analysed by multiple individuals to ensure that all researchers arrived at the same conclusions. The group allocation was not revealed until after the analysis. Nevertheless, the alleviation of rater blinding could have possibly introduced detection bias.

No reliable German outcome measures exist specifically for people with intellectual disabilities for these outcomes. However, based on the experiences in previous projects [97], during the pre-test and during data collection, we assume that the participants understood the assessments reasonably well, and therefore data collection was reliable.

Deviations from protocol

We intended to use the 36-item version of the WHODAS; however, data on items addressing problems at work were largely incomplete or highly unreliable, with responses such as "I can only guess" being common. Consequently, we only analysed the 32-item version of the WHODAS, which excluded questions on work. This has no impact on the quality or interpretation of the data [62]. Two advanced practice nurse positions could not be filled with nurses and were

therefore labelled as health experts. They always worked in tandem with a nurse.

Conclusions

To our knowledge, this study is the first randomized-controlled trial of a nurse-led case management and prevention intervention for people with intellectual disabilities. Despite the limitations and challenges associated with the German healthcare system and specialised nursing roles, prevention and case management provided by advanced practice nurses and health experts can lead to clinically meaningful improvements in the health of people with intellectual disabilities over twelve months. Consequently, the intervention can support them to achieve greater equality and participation in healthcare, which is in line with the United Nations Convention on the Rights of Persons with Disabilities. People with intellectual disabilities have lower levels of health, resilience, and health-related quality of life. Practitioners and researchers alike should focus on eliciting reasons and developing tailored interventions.

Availability of data

The anonymized data are available at the [blinded] repository [blinded].

Conflict of interest

None.

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Tables & Figures

Table 1 – Advanced practice nurse's and health experts' qualification

Advanced practice nurse	Master's degree	Master's degree (year)	Experience as a registered nurse (years)	Experience with the target group (years)
1	Medical pedagogics	2024	2	0
2	Nursing science and management (main focus: advanced practice nursing)	2023	2	0
3	Medical pedagogics	2020	6	0
4	Health services research and design	2022	0.5	0
5	Healthcare and nursing pedagogics	2025	5	0
6	Nursing science and management (main focus: advanced practice nursing)	2022	2	0
7	Acute care	2022	9	0
8	Healthcare and nursing pedagogics	2020	12	4
Health Expert				
1	Public Health	2017	0	0
2	Prevention and health promotion	2017	0	0

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Table 2 - Baseline data

Variable		Intervention group (n=102)	Control group (n=103)	Total (n=205)	p-value (group differences)
Age in years, mean±SD*		40.27±12.0	42.34±12.6	41.31±12.3	0.231**
Sex, female n (%)		56 (54.9)	53 (51.5)	109 (53.2)	0.621***
Living situation, n (%)	Alone	33 (32.4)	28 (27.5)	61 (29.9)	0.854****
	With family	6 (5.9)	7 (6.9)	13 (6.4)	
	Ambulatory setting	39 (38.2)	44 (43.1)	83 (40.7)	
	Residential setting	24 (23.5)	23 (22.5)	47 (23.0)	
Daily Support, n (%) (multiple choice)	None	0 (0.0)	0 (0.0)	0 (0.0)	0.945***
	Family/ friends/ neighbours	62 (60.8)	59 (57.8)	121 (59.6)	
	Professional	92 (90.2)	96 (94.1)	188 (92.6)	
District of Hamburg, n (%)	Altona	8 (7.8)	5 (4.9)	13 (6.3)	0.525****
	Bergedorf	17 (16.7)	10 (9.7)	27 (13.2)	
	Eimsbüttel	8 (7.8)	8 (7.8)	16 (7.8)	
	Harburg	5 (4.9)	9 (8.7)	14 (6.8)	
	Mitte	14 (13.7)	20 (19.4)	34 (16.6)	
	Nord	19 (18.6)	23 (22.3)	42 (20.5)	
	Wandsbek	31 (30.4)	28 (27.2)	59 (28.8)	
WHODAS domain cognition (0-100, high= more disability), mean±SD		35.74±18.8	36.12±18.0	35.93±18.3	0.882**
WHODAS domain mobility (0-100, high= more disability), mean±SD		22.67±25.6	26.4±28.2	24.54±26.9	0.323**
WHODAS domain self-care (0-100, high= more disability), mean±SD		19.61±20.8	19.81±23.9	19.71±22.3	0.950**
WHODAS domain getting along (0-100, high= more disability), mean±SD		37.50±27.3	40.37±25.0	38.94±26.1	0.433**
WHODAS domain life activities (0-100, high= more disability), mean±SD		54.12±28.4	48.74±30.3	51.41±29.4	0.191**
WHODAS domain participation (0-100, high= more disability), mean±SD		43.22±18.2	39.64±16.4	41.42±17.4	0.141**
Outcomes					
Health status (WHODAS, 0-100, high= more disability), mean±SD		35.89±14.5	35.50±14.9	35.70±14.7	0.231**

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Resilience (RS-11, 7-77, high= more resilience) mean±SD	53.41±9.5	54.85±9.5	54.13±9.5	0.621**
Health-related quality of life (EQ5D, self report, 0-100, high = more quality of life) mean±SD	66.69±19.7	66.67±22,9	66.68±21.3	0.850**
Health-related quality of life (EQ5D, proxy, 0-100, high = more quality of life) mean±SD	67.13±17.4	61.07±14.9	64.08±18.2	0.017**

* SD= standard deviation, significance testing performed with **two-sided independent t-test, ***chi-square test and ****Fisher's exact test.

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Table 3 - Outcome Data T1 and T2

Variable	Intervention group	Control group	MD* (adjusted for covariate)	97,5% CI** for adjusted MD	p-value***	Partial eta-squared
<i>T1</i>	<i>n=92</i>	<i>n=93</i>				
Health status (WHODAS, 0-100, high= more disability), mean±SD****	36.00±15.9	37.03±15.5	-1.06	-3.51 to 5.62	0.602	0.002
Resilience (RS-11, 7-77, high= more resilience) mean±SD	53.88±9.4	54.29±9.7	+0.51	-3.11 to 2.10	0.660	0.001
Health-related quality of life (EQ5D, self report, 0-100, high = more quality of life) mean±SD	69.90±22.7	69.09±23.6	+0.72	-5.88 to 7.32	0.805	0.000
Health-related quality of life (EQ5D, proxy. 0-100, high = more quality of life)) mean±SD	66.52±19.7	64.34±19.8	-0.91	-6.63 to 4.80	0.718	0.001
<i>T2</i>	<i>n=83 (proxy assessments n=77)</i>	<i>n=90</i>				
Health status (WHODAS, 0-100, high= more disability), mean±SD	32.30±13.1	36.88±15.2	-4.38	-8.13 to -0.62	0.009	0.041
Resilience (RS-11, 7-77, high= more resilience) mean±SD	55.18±10.5	53.21±11.1	+2.70	-5.78 to 0.39	0.050	0.022

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Health-related quality of life (EQ5D, self report, 0-100, high = more quality of life) mean±SD	67.17±23.9	68.14±25.4	-1.19	-8.71 to 6.33	0.720	0.001
Health-related quality of life (EQ5D, proxy, 0-100, high = more quality of life) mean±SD	65.81±19.5	61.89±20.8	+0.78	-5.17 to 6.73	0.766	0.001

*Mean difference (MD) for the adjusted for covariate (Baseline value of variable (t0)), **CI =confidence interval, ***p-value of ANCOVA for the group effect, **** SD= standard deviation.

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Figure 1 – CONSORT flow chart

