Cost-effectiveness of a transdiagnostic group exercise intervention for mental health in Germany (ImPuls trial): an economic evaluation study

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Summary

Background Standard treatments for mental health outpatients have high non-response rates and are often difficult to access. Exercise therapy has shown effectiveness in this population, but evidence on its cost-effectiveness is scarce and mixed across studies. This study aimed to assess the cost-effectiveness of ImPuls, a transdiagnostic group exercise intervention for outpatients with common mental disorders.

Methods This study was part of the multicentre, randomised controlled trial (n=400) comparing ImPuls plus treatment as usual (TAU) with TAU alone in German outpatient care. Participants (aged 18–65 years) had a diagnosis of moderate or severe depression, primary insomnia, post-traumatic stress disorder, panic disorder, or agoraphobia. ImPuls was a 6-month transdiagnostic group exercise intervention that included supervised group-based aerobic exercise (weeks 0–4) and unsupervised group and exercise activities supported by targeted behavioural and educational strategies, regular therapist calls, and a smartphone application (weeks 5–24). Global symptom severity, which was the primary outcome of the initial trial (measured using the Brief Symptom Inventory [BSI-18]), and health-related quality of life were assessed at baseline, 6 months, and 12 months. Health-care costs were analysed on the basis of statutory health insurance claims data. For the cost-effectiveness analysis, incremental total costs and incremental changes in BSI-18 and quality-adjusted life-years (QALYs) were estimated; QALYs were calculated from EQ-5D-5L utility values. Cost-effectiveness and cost-utility analyses were assessed at 12 months from the statutory health insurance perspective on an intention-to-treat basis, using the incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR). The study is part of the preplanned analysis of the the ImPuls trial (registered with the German Clinical Trials Register as DRKS00024152). People with lived experience were not involved in the study design, conduct, and reporting.

Findings Of the 400 individuals in the ImPuls trial, claims data were available for 389 participants. Mean total health-care costs were €8932 (SD 13 688) in the intervention group and €7168 (9489) in the control group in the 12 months before baseline, and €5556 (7370) in the intervention group and €5683 (SD 7487) in the control group in the 12-month follow-up. There were no significant differences in health-care use or unadjusted costs among the cost categories, with the exception of inpatient hospital costs (€–1324; bootstrapped 95% CI –2504 to –215), and no significant difference in total statutory health insurance costs between ImPuls plus TAU and TAU alone. At 12 months, ImPuls plus TAU achieved better outcomes than TAU alone, with a –3·78-point (95% CI –5·91 to –1·65) greater reduction in BSI-18 scores and a quality-adjusted life-years (QALYs) gain of 0·032 (95% CI 0·005 to 0·058). Including intervention costs, the estimated incremental difference in total costs at 12 months was €553 higher in the intervention group (95% CI –148 to 1255), corresponding to an ICER of €146 per BSI-18 point reduction and an ICUR of €17 543 per QALY. Assuming a willingness-to-pay threshold of €30 000 per QALY in Germany, the probability of ImPuls being cost-effective was 77%. The sensitivity analyses produced similar results.

Interpretation ImPuls shows promise as a cost-effective transdiagnostic group-based exercise intervention for improving mental health in outpatient care when added to TAU. It could be considered for implementation alongside standard outpatient services.

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Introduction

The Global Burden of Diseases, Injuries, and Risk Factors 2019 study estimated the burden attributed to the sum of mental health conditions, such as depression, insomnia, anxiety, and stress-related disorders, to amount to 4·9% of all disability-adjusted life-years.[1] In another study, this share was estimated to be 16·0%, corresponding to economic costs of up to US$5 trillion for

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Research in context

Evidence before this study

There is a growing body of evidence supporting the effectiveness of exercise interventions for mental health conditions such as depression, insomnia, stress-related disorders, and anxiety disorders. The ImPuls trial showed that a transdiagnostic group-based exercise programme, when added to treatment as usual, was superior to treatment as usual alone in reducing symptom severity in German outpatients with moderate or severe depression, post-traumatic stress disorder (PTSD), panic disorder, agoraphobia, or insomnia. There is still little evidence on the cost-effectiveness of exercise and physical activity interventions. A 2025 systematic review by Alhusseini and colleagues identified 11 studies on physical activity interventions for mental health, which varied widely in terms of intervention type, study population, and setting. The authors concluded that the current evidence base is insufficient to identify whether such interventions are cost-effective, emphasising the need for more rigorous studies. In addition, we considered relevant publications from a 2021 review by Le and colleagues on the cost-effectiveness of mental health prevention and promotion interventions, supplemented by a PubMed search done in March 2024 with no date restrictions (updated April 2025), using the following terms: (cost-effectiveness[Title/Abstract] OR health economic evaluation[Title/Abstract]) AND (exercise[Title/Abstract] OR physical activity[Title/Abstract]) AND (mental health[Title/Abstract] OR depression[Title/Abstract] OR transdiagnostic[Title/Abstract] OR PTSD[Title/Abstract] OR agoraphobia[Title/Abstract] OR panic disorder[Title/Abstract] OR primary insomnia[Title/Abstract]). No language restrictions were applied. Studies were excluded if the intervention included additional components beyond exercise or physical activity, if the study population was defined by subclinical mental health symptoms or other comorbid conditions, or if the interventions were not compared with treatment as usual. We found four cost-effectiveness studies with mixed findings. Exercise therapy appeared to be cost-effective for people with mild to moderate depression in Swedish primary care, but no favourable cost-effectiveness results were reported for UK outpatients with diagnosed depression in a programme targeting young people with mild to moderate depression, or in a Dutch outpatient intervention for major depressive disorder. No study examined the cost-effectiveness of exercise therapy in a transdiagnostic setting.

Added value of this study

To our knowledge, this is the first study to analyse both the costs and cost-effectiveness of a transdiagnostic exercise programme for mental health outpatients. The intervention was implemented alongside treatment as usual and was compared with treatment as usual alone. Although total health-care costs after 12 months were €553 higher per participant in the intervention group, we found favourable cost-effectiveness results from the statutory health insurance perspective (base case: €17 543 per QALY). A key advance over previous studies is that we provide cost-effectiveness evidence for exercise therapy in a transdiagnostic mental health population. The large sample size, the confirmation of clinical inclusion diagnoses through diagnostic interviews, the use of health insurance claims data rather than self-reported data for health-care costs, and the pragmatic implementation of the intervention alongside treatment as usual strengthen the robustness and generalisability of our findings.

Implications of all the available evidence

Existing evidence on the efficacy of exercise interventions, previous findings on their cost-effectiveness, and the new results from our study indicate that exercise interventions can serve as effective and economically viable add-ons to standard therapies for mental health conditions. Our study extends previous evidence to a transdiagnostic population, including people with depression, panic disorder, agoraphobia, PTSD, or insomnia. Further research is needed to clarify the optimal role of such interventions—whether as add-ons or standalone options—and to compare exercise-based approaches, such as ImPuls, with other transdiagnostic psychological treatments to establish where they can be implemented most cost-effectively.

the year 2019.[2] In 2018, 84 million people in the EU were living with such conditions, with associated costs equivalent to 4% of gross domestic product, or approximately €600 billion.[3] However, individuals with mental health problems have limited access to evidence-based standard pharmacological treatments and psychotherapy.[4] At the same time, low response rates to standard treatments are often reported, such as 56% for pharmacotherapy for general anxiety disorder and 54% for psychotherapy for major depressive disorders.[5] Additional treatment options are therefore needed. Given constrained health-care resources, such options should also demonstrate cost-effectiveness to justify large-scale implementation in publicly funded systems. Physical (motor) activity and exercise have been identified as a promising approach, with evidence of effectiveness for several conditions, including depression, post-traumatic stress disorder (PTSD), insomnia, and anxiety disorders.[6–8] However, there is little evidence on the cost-effectiveness of exercise interventions, and existing evidence is mixed, as reported in a recent systematic review.[9] The review identified 11 studies that differed widely in terms of intervention type, study population, and setting, which limits comparability and generalisability. Four studies focused on clinical mental health conditions only, with exercise as the sole intervention component and treatment as usual (TAU) as the comparator. Exercise therapy was cost-effective for individuals with mild to moderate depression in Swedish primary care,[10] but not in Dutch outpatients with major

depressive disorder.[11] No favourable cost-effectiveness results were reported in the UK for physical activity counselling for outpatients diagnosed with depression[12] and for community-based exercise for young people with mild to moderate depression.[13] To date, no study has examined the cost-effectiveness of an exercise intervention in a transdiagnostic setting.

ImPuls was a large, pragmatic, multisite, block-randomised, phase 3 controlled trial in Germany that tested a group-based exercise intervention for outpatients with different mental disorders.[8] When added to TAU, the intervention demonstrated superior efficacy compared with TAU alone: participants in the intervention group showed significantly higher improvements of 4·11 (95% CI 1·74–6·48) in global symptom severity measured using the Brief Symptom Inventory (BSI-18) at 6-month follow-up (primary endpoint) and of 3·29 (0·86–5·72) at 12-month follow-up, and a higher proportion of participants had clinically significant changes. No significant differences were found between groups in the total number of adverse events or serious adverse events.[8] Given these favourable efficacy and safety results, it is important to assess whether ImPuls represents a cost-effective use of health-care resources. Features that might support its cost-effectiveness include the group-based, partly supervised delivery format and the potential for longer term benefits through sustained motivation and volition for physical exercise. The present study, therefore, analyses the costs and cost-effectiveness of the ImPuls intervention using data from the published efficacy trial and statutory health insurance (SHI) claims. We tested whether ImPuls reduces overall health-care costs or, alternatively, can be considered cost-effective from the SHI perspective.

Methods

Study design and participants

This cost-effectiveness analysis was conducted as part of the ImPuls trial, the efficacy results of which have been published previously.[8] We assessed health-care costs on the basis of claims data, intervention costs, and health outcomes, and we evaluated the cost-effectiveness and cost-utility of the ImPuls intervention at 12 months from the SHI perspective. The analysis population comprised all randomly assigned participants on an intention-to-treat basis, as in the primary efficacy analysis,[8] but it excluded individuals for whom claims data were not available. The methodological approach followed the Consolidated Health Economic Evaluation Reporting Standards checklist and the General Methods (version 7.0) of the German Institute for Quality and Efficiency in Health.[14,15] All participants provided written informed consent, including consent for the use of insurance claims data. The ImPuls trial, including the health economic analysis, was approved by the local ethics committee of the University of Tübingen (approval number 888/2020B01; Nov 2, 2020). The health economic analysis was prespecified in the published trial protocol.[16] The study is registered with the German Clinical Trials Register (number DRKS00024152).

ImPuls intervention

The ImPuls trial was a phase 3, block-randomised controlled trial with two groups (ImPuls plus TAU *vs* TAU alone). It was conducted at centres of psychosomatic, orthopaedic, or cardiological rehabilitation, and one outpatient physiotherapy unit in Baden-Württemberg, Germany. Recruitment took place between Jan 1, 2021, and May 31, 2022. Eligible participants were aged 18–65 years, had an ICD-10 diagnosis of moderate or severe depression, primary insomnia, PTSD, panic disorder, or agoraphobia confirmed through structured clinical interviews by trained psychotherapists. Participants had to be insured with the health insurance companies Allgemeine Ortskrankenkassen (known as AOK) Baden-Württemberg or Techniker Krankenkasse (known as TK), which have a combined coverage of 60% of citizens with public health insurance in Baden-Württemberg (88% of citizens are publicly insured). Exclusion criteria were insufficient German language fluency or medical contraindications for exercise therapy. A broad recruitment strategy with various instruments was applied, such as promotional material at the study sites and at primary care physicians and psychotherapists in the region, as well as promotional activities through the involved health insurers, social media, print media, and television. At each study site, blocks of six participants were randomly assigned (1:1) to ImPuls plus TAU or TAU alone using a sequence generated by an external data officer and concealed from data collection and management staff.

Exercise therapists received training for the ImPuls programme before the start of the trial. Participants of the trial were allocated to groups of six after the block randomisation. The 6-month ImPuls intervention included a supervised (weeks 0–4) and a partly supervised phase (weeks 5–24) to promote sustained physical activity. In the first 4 weeks, participants engaged in ten supervised group sessions (120 min each), which, apart from the first session, included moderate-to-vigorous outdoor aerobic exercise and twice per week unsupervised exercise (≥30 min). From weeks 5 to 12, the plan was for participants to engage in unsupervised exercise (at least twice per week). To promote exercise adherence, this plan was supported by training plans, activity diaries, once per week therapist calls, unsupervised group sessions twice per month, and one supporters' session (family members or friends identified by participants). In weeks 13–24, unsupervised exercise (at least twice per week) was supported by two therapist calls per month. The supervised and unsupervised phases were complemented by education and motivational and volitional behavioural change techniques such as goal setting, self-monitoring, and

See Online for appendix

coping planning (appendix p 28). A smartphone application facilitated goal setting, exercise planning, self-monitoring, and secure data sharing between participants and therapists during the intervention phase. The minimum intervention dose was defined as receiving at least 2 complete weeks of the 4-week supervised intervention phase. TAU reflected standard outpatient care in Germany, allowing access to psychological and pharmacological treatments as available. Further details of the intervention and trial design are presented in the appendix (pp 24–29) and are published elsewhere.[8,16]

Data collection and extraction

Study participants completed online surveys at baseline, 6 months, and 12 months, including the validated German versions of the BSI-18 and the EQ-5D-5L questionnaire.[17,18] The BSI-18 is a short form of the symptom checklist 90, one of the most widely used instruments for transdiagnostic assessment of general psychological distress. The primary outcome of the ImPuls trial was global symptom severity, measured at 6 months using the Global Severity Index (GSI), derived from the validated German version of the BSI-18, which gives a measure of general mental distress across symptom scales for somatisation, depression, and anxiety. The EQ-5D-5L was used to assess health-related quality of life. Online survey administration and data storage were conducted using RedCAP.

A micro-costing approach was applied to estimate intervention costs, including exercise therapy sessions, the initial assessment, the ImPuls smartphone application, and training of exercise therapists (appendix p 3). Health-care costs were derived from claims data provided by two large statutory health insurers (AOK Baden-Württemberg and TK) covering the year before and the year after random assignment. Cost categories were outpatient cases, psychotherapy, prescriptions for psychotropic and cardiological medications, inpatient psychiatric and cardiological hospital cases, and sick leave related to psychological diagnoses (appendix p 2).

	ImPuls plus TAU (n=190)	TAU (n=199)
Self-reported data from primary data collection		
Female	135 (71%)	141 (71%)
Male	55 (29%)	58 (29%)
Secondary education or lower	122 (64%)	129/196 (66%)
Tertiary education	68 (36%)	67/196 (34%)
Moderate or severe depression (ICD-10 F32.1, F32.2, F331, and F33.2)	141 (74%)	139 (70%)
Panic disorder (ICD-10 F41.0)	22 (12%)	20 (10%)
Agoraphobia (ICD-10 F40.0 and F40.01)	19 (10%)	18 (9%)
Post-traumatic stress disorder (ICD-10 F43.1)	30 (16%)	41 (21%)
Primary insomnia (ICD-10 F.51.0)	42 (22%)	37 (19%)
Brief Symptom Inventory 18	22·11 (11·84)	22·09 (10·58)
EQ-5D-5L index	0·73 (0·21)	0·73 (0·20)
Information extracted from claims data		
Age, years	42·29 (12·80)	43·14 (13·68)
Voluntarily insured in SHI	26 (14%)	23/197 (12%)
Regularly insured in SHI	164 (86%)	174/197 (88%)
Charlson Comorbidity Index based on outpatient diagnoses in 12 months before baseline	0·46 (1·09)	0·40 (0·77)
Any psychological treatment in the 12 months before baseline	115 (61%)	117 (59%)
Any psychopharmacological prescription in the 12 months before baseline	91 (48%)	81 (41%)
SHI costs in 12 months before baseline in €	8932 (13 688)	7168 (9489)

Data are n (%) or mean (SD). Age was missing for four individuals in claims data and supplemented by information from primary data. Voluntary insurance, available only to individuals with a gross income higher than €64 350 per year (in 2022), served as a proxy for income. Charlson Comorbidity Index was calculated using Quan weights, and has a theoretical range of 0–24, with higher scores indicating a greater comorbidity burden. Differences in reported values, for example those relating to current treatment, compared with the published efficacy analysis arose due to the nature of the data sources (self-reported *vs* claims data) and the smaller sample (389 *vs* 400). SHI=statutory health insurance. TAU=treatment as usual.

Table 1: **Descriptive statistics of participants at baseline**

Data analysis

Health-care use and costs were calculated for each category and in total for three periods: the 12 months before baseline, and 6 months and 12 months after baseline. For participants who switched insurers during the study (n=5), costs from incomplete observation periods were linearly extrapolated to cover the full period. All costs were adjusted to 2023 euros. The adjusted difference in total health-care costs was estimated using a generalised linear mixed model with Tweedie distribution and log-link (glmmTMB package in R).[19] The model included categorical fixed effects for time (baseline, 6 months, and 12 months), group (intervention *vs* control), and interactions between time and group. Random intercepts were included at both the participant and site levels to account for the hierarchical structure of the data. Random slopes led to overfitting of the right-skewed cost data (appendix p 4). Thus, these were not included in the final model. For each of the different health-care cost categories included in the total health-care costs, non-adjusted mean differences in changes from baseline to 12 months between the ImPuls plus TAU and TAU alone groups were calculated.

For the cost-effectiveness analysis, incremental total costs and incremental changes in BSI-18 and quality-adjusted life-years (QALYs) at 12 months were estimated. One QALY represents 1 year of life in full health. QALYs were calculated from EQ-5D-5L utility values using the German tariff,[20] applying the area-under-the-curve method.[21] Missing BSI-18 and EQ-5D-5L utility values were imputed using multilevel multiple imputation by chained equations with ten imputed datasets and 20 iterations per dataset.[22] Two-level predictive mean matching accounting for clustering of repeated measurements within participants was applied. In addition to self-reported outcome variables and further patient-reported outcomes, the imputation included

patient characteristics, such as the mental health inclusion diagnoses, gender, age, and treatments. The imputation was identical to the imputation used in the efficacy trial, with the exception that EQ-5D-5L utility values were included in the present analysis. After imputation, analyses were performed separately in each imputed dataset and combined using Rubin's rules to produce pooled estimates. The incremental effectiveness of ImPuls plus TAU compared with TAU alone was assessed separately for BSI-18 and EQ-5D-5L utilities using linear mixed models with fixed effects for time (baseline, 6 months, and 12 months), group (intervention *vs* control), and the interactions between time and group; random intercepts to account for between-person and between-site variation; and random slopes for time-related between-person variation. Models were estimated with the lme4 package in R. Final incremental effect estimates were derived from marginal means of the respective linear mixed models. Incremental total costs (defined as total health-care costs plus intervention costs) were estimated using the same model as for total health-care costs. Due to the longitudinal structure of the specification of outcome and cost models, also known as mixed model for repeated measurement, differences in baseline outcomes or costs are adjusted for.[23]

To account for skewed cost distributions (appendix p 5) and the correlation between costs and effects while also estimating average treatment effects and the uncertainty of cost-effectiveness and cost-utility estimates, pairwise non-parametric bootstrapping was applied.[23,24] The analysis was repeated 2000 times with replacement. Estimates of incremental effects and total costs (ImPuls plus TAU *vs* TAU alone) were pooled across the imputed datasets. Ratios of mean incremental costs to mean incremental effects on BSI-18 and QALYs constituted the central cost-effectiveness (incremental cost-effectiveness ratio [ICER]) and cost-utility (incremental cost-utility ratio [ICUR]) estimates, expressed as cost per one-point change in BSI-18 and cost per QALY gained. Bootstrapped pairs of incremental costs and effects were plotted on cost-effectiveness planes; and, for QALYs, a cost-effectiveness acceptability curve was generated using thresholds from €0 to €80 000 per QALY. There is no official cost-per-QALY threshold in Germany, but empirical estimates for Germany and thresholds from similar countries suggest that interventions with ICURs of €20 000–40 000 might be considered cost-effective.[25]

In addition to the base case analysis, seven post-hoc sensitivity analyses were conducted. First, implementation costs were calculated using the actual costs for smartphone application maintenance and training of exercise therapists observed in the trial, allocated to the number of participants in the intervention group rather than the projected routine-care costs used in the base case. Second, the costs of conducting a Structured Clinical Interview for DSM Disorders (SCID) by psychotherapists were added to the intervention costs. The SCID was part of the screening process for the trial in both the intervention and control groups. Calculations of intervention costs for these two sensitivity analyses are described in the appendix (p 3). Third, control variables (age, gender, and comorbidities) were added to the cost and effect regressions; comorbidity was measured with the Charlson Comorbidity Index on the basis of outpatient diagnoses in the 12 months before baseline.[26] Fourth, per-patient costs above the 95th percentiles in each cost category (eg, inpatient costs) were capped at the 95th percentile value. Fifth, the analysis was restricted to cost categories related to mental health care, including outpatient cases with a recorded psychiatric diagnosis, psychotherapy, hospitalisations for a psychiatric

	Mean (SD) in €		Unadjusted mean difference between groups (95% CI)	Adjusted difference (95% CI)*
	ImPuls plus TAU (n=190)	TAU (n=199)		
Total sum of all statutory health insurance costs				
Baseline	8932 (13 688)	7168 (9489)	..	..
12 months follow-up	5556 (7370)	5683 (7487)	..	−312 (−919 to 296)
Cost category: outpatient medical care (except psychotherapy)				
Baseline	1601 (2742)	1685 (1573)	..	..
12 months follow-up	1581 (2570)	1506 (1402)	160 (−88 to 391)	..
Cost category: outpatient psychotherapeutic care				
Baseline	1362 (1715)	1420 (1797)	..	..
12 months follow-up	1253 (1745)	1295 (1833)	16 (−306 to 331)	..
Cost category: inpatient care with F-diagnosis				
Baseline	1963 (6500)	953 (3695)	..	..
12 months follow-up	839 (3259)	1153 (4312)	−1324 (−2504 to −215)	..
Cost category: inpatient care with I-diagnosis				
Baseline	45 (539)	184 (1985)	..	..
12 months follow-up	100 (824)	144 (1579)	95 (−247 to 556)	..
Cost category: psychopharmacological prescriptions				
Baseline	74 (182)	64 (148)	..	..
12 months follow-up	96 (216)	101 (169)	−15 (−42 to 16)	..
Cost category: cardiological prescriptions				
Baseline	14·4 (48·6)	11·0 (42·9)	..	..
12 months follow-up	21·3 (63·7)	28·1 (157·1)	−10·2 (−55·6 to 3·3)	..
Cost category: sick pay				
Baseline	3856 (9966)	2847 (7611)	..	..
12 months follow-up	1666 (5083)	1456 (5044)	−799 (−2597 to 865)	..

Data are mean (SD), unless otherwise stated. Baseline refers to the 12 months before baseline. F-diagnoses are mental and behavioural disorders; I-diagnoses are diseases of the circulatory system. 95% CIs of unadjusted mean differences between groups were calculated using non-parametric bootstrapping. TAU=treatment as usual. *Adjusted difference calculated based on generalised linear mixed model regression.

Table 2: **Descriptive and analytical results of statutory health insurance cost analysis**

	Estimate (95% CI)		Adjusted difference (95% CI)
	ImPuls plus TAU (n=190)	TAU (n=199)	
Brief Symptom Inventory 18			
6 months	15·3 (13·9 to 16·6)	19·6 (18·4 to 20·9)	−4·38 (−6·44 to −2·32)
12 months	14·6 (13·2 to 16·1)	18·4 (17·1 to 19·8)	−3·78 (−5·91 to −1·65)
EQ-5D-5L			
6 months	0·758 (0·727 to 0·789)	0·716 (0·691 to 0·742)	0·042 (−0·001 to 0·085)
12 months	0·771 (0·743 to 0·799)	0·729 (0·700 to 0·758)	0·043 (0·000 to 0·085)
QALYs			
12 months	0·754 (0·735 to 0·774)	0·723 (0·707 to 0·739)	0·032 (0·005 to 0·058)
Total costs in €			
6 months	2588 (2238 to 2938)	1990 (1724 to 2255)	598 (116 to 1080)
12 months	4175 (3702 to 4648)	3622 (3231 to 4012)	553 (−148 to 1255)

Results are based on bootstrapped estimates from linear mixed models (BSI-18 and EQ-5D-5L) and generalised linear mixed model (costs) regressions. Estimates and adjusted differences represent estimated marginal means. Total costs are statutory health insurance costs plus intervention costs. ICER=incremental cost-effectiveness ratio. ICUR=incremental cost-utility ratio. QALY=quality-adjusted life year. TAU=treatment as usual.

Table 3: **Bootstrapped incremental effects, costs, and corresponding cost-effectiveness ratios**

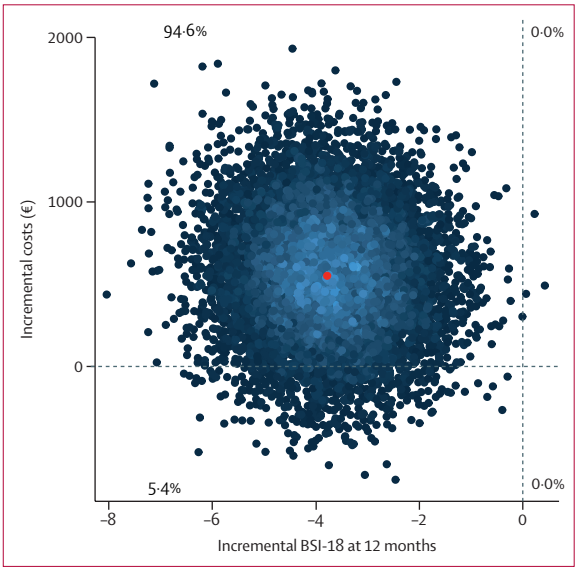

Figure 1: **Cost-effectiveness plane for BSI-18 at 12 months comparing ImPuls plus TAU with TAU**

Percentages in each corner represent the share of bootstrapped results falling in the respective quadrant. Red dot corresponds to the central incremental cost-effectiveness ratio of €146 per BSI-18 point change. BSI-18=Brief Symptom Inventory 18. TAU=treatment as usual.

diagnosis, prescriptions for psychopharmaceuticals, and sick leave attributed to a psychiatric diagnosis. Furthermore, complete case and per-protocol analyses were conducted on the non-imputed data. All analyses were conducted using R version 4.5.0.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

In the ImPuls trial, 400 individuals were randomly assigned to ImPuls plus TAU (n=199) or TAU alone (n=201). The trial was conducted between Jan 1, 2021 (first participant recruited) and Nov 30, 2022 (end of intervention period of last participant). One participant in the intervention group withdrew consent. Claims data were available for 389 participants. Reasons for missing data could not be disclosed by the health insurers. Of these participants, 113 (29%) were men and 276 (71%) were women, and 360 (93%) had German citizenship, with a mean age of 42·7 years (range 19–66 years). Baseline characteristics by treatment group are shown in table 1. Across all three timepoints, missing values requiring imputation amounted to 11% (129 of 1167) for BSI-18 and 12% (137 of 1167) for EQ-5D-5L. A data missingness flowchart, including the composition of complete cases and per-protocol analysis, is included in the appendix (p 6). Additional descriptive statistics for the full trial population are reported in the primary efficacy publication.[8]

Mean total health-care costs were €8932 (SD 13 688) in the intervention group and €7168 (9489) in the control group in the 12 months before baseline, and €5556 (7370) in the intervention group and €5683 (SD 7487) in the control group in the 12-month follow-up (table 2). The corresponding unadjusted mean cost differences were €–3371 (bootstrapped 95% CI –5183 to –665) in the intervention group and €–1466 (–2858 to –154) in the control group, with reductions primarily occurring in sick pay and inpatient costs.

Unadjusted mean difference in cost changes from baseline to 12 months between ImPuls plus TAU and TAU alone were not statistically significant for all cost categories (table 2), except for inpatient cases with an F-diagnosis (mental and behavioural disorder) as main or admission diagnosis, who had a mean difference of €–1324 (bootstrapped 95% CI –2504 to –215). No significant differences were found for the number of claimed cases or sick days over all cost categories (appendix p 7). The generalised linear mixed model estimate of the adjusted difference in total health-care costs between ImPuls plus TAU and TAU alone was €–312 (95% CI –919 to 296; p=0·31). The mean intervention cost of ImPuls was €653 (SD 280) per participant, most of which was incurred during the first 4 weeks (appendix p 3).

In the analysis sample of 389 participants, ImPuls plus TAU was superior to TAU alone on the BSI-18 (table 3). The bootstrapped incremental effect after 12 months was a reduction of –3·78 points (95% CI –5·91 to –1·65). This estimate differs slightly from that in the primary efficacy analysis (–3·29, –5·72 to –0·86) due to the imputation procedure incorporating EQ-5D-5L values, and the smaller analysis sample (389 *vs* 399 participants). The estimated incremental improvement in EQ-5D-5L utility was 0·042 (95% CI –0·001 to 0·085) at 6 months and 0·043 (95% CI 0·000 to 0·085) at 12 months, corresponding to an incremental QALY gain of 0·032 (95% CI 0·005 to 0·058) over 12 months. The estimated incremental difference in total costs (intervention plus SHI claims) at 12 months was €553 higher in the intervention group (95% CI –148 to 1255). These incremental costs and effects translated into an ICER of €146 per BSI-18 point change and an ICUR of €17 543 per QALY.

The cost-effectiveness planes of the bootstrapped pairs of incremental costs and effects (BSI-18 point change and QALYs) illustrate the degree of uncertainty in the ICER and ICUR (figures 1 and 2), with greater variability observed in the cost estimates. The corresponding cost-effectiveness acceptability curve indicates that, at QALY threshold values of €20 000, €30 000, and €40 000, the probability of ImPuls being cost-effective was 57%, 77%, and 86%, respectively (figure 3).

Results from the sensitivity analyses were broadly consistent with the base case findings and are described in more detail in the appendix (pp 8–10). Two scenarios relating to the calculation of the intervention costs produced less favourable cost-effectiveness estimates. First, using actual smartphone application maintenance costs and allocating intervention costs only to the number of intervention participants in the trial resulted in an ICER of €184 per BSI-18 point change and an ICUR of €22 032 per QALY. Second, including the costs of conducting a comprehensive diagnostic interview (SCID) before the intervention increased the ICER to €201 per BSI-18 point change and the ICUR to €24 068 per QALY. Complete case analysis, per-protocol analysis, and an analysis excluding individuals with PTSD resulted in more favourable ICUR estimates of €15 438, €15 228, and €15 238, respectively. The probabilities of ImPuls being cost-effective at these thresholds for these sensitivity analyses are shown in the appendix (pp 8–10).

To provide an indication for the cost-effectiveness of ImPuls after 1-year costs and effects, we performed a simple extrapolation of the study results to the time frame of 24 months. Assuming that the incremental quality of life gain after 12 months would linearly decrease to zero after 24 months and that no differences in health-care costs would occur in that period (after results from the cost analysis), this would result in an ICUR estimate of €12 579 per QALY after 24 months (appendix p 11).

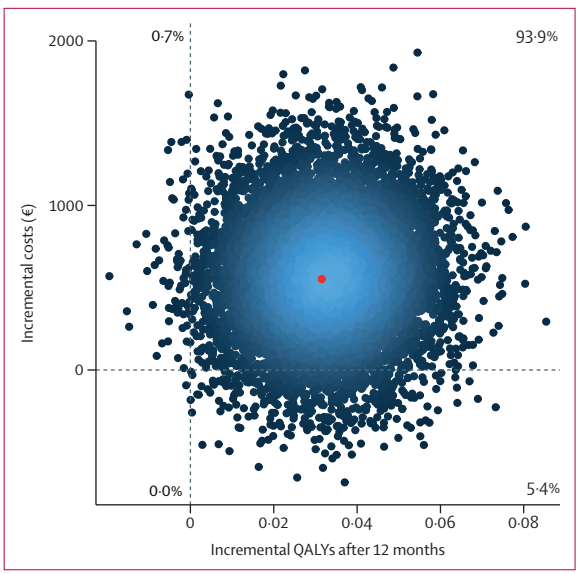

Figure 2: **Cost-effectiveness plane for QALYs after 12 months comparing ImPuls plus TAU with TAU**
Percentages in each corner represent the share of bootstrapped results falling in the respective quadrant. Red dot corresponds to the central incremental cost-utility ratio of €17 543 per QALY. QALY=quality-adjusted life year. TAU=treatment as usual.

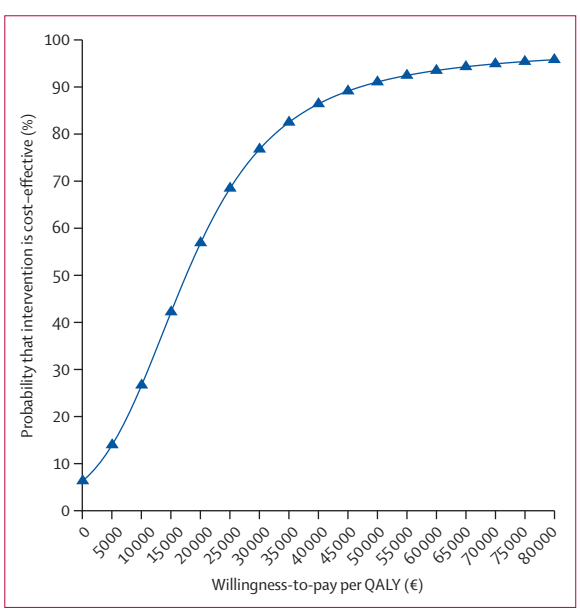

Figure 3: **Cost-effectiveness acceptability curve for QALYs after 12 months comparing ImPuls plus TAU with TAU**
QALY=quality-adjusted life year. TAU=treatment as usual.

Discussion

In our examination of the costs and the cost-effectiveness of ImPuls, a group-based exercise intervention for outpatients with mental disorders, we found no significant differences in health-care use or unadjusted costs among the included cost categories, with the exception of mental-health-related hospital costs, and no

significant difference in total SHI costs (excluding intervention costs) between ImPuls plus TAU and TAU alone. The marked decrease in sick pay costs compared with the previous observation period in both groups might be partly explained by an increasing number of people who reach the statutory limit of 78 weeks of sick pay within 3 years or take (early) retirement. This explanation cannot reliably be illustrated with the available data. Another explanation, which also applies to the marked decrease in hospital costs in both groups, could be the (temporal) connection between the occurrence of psychological problems and participation in the study. One reason for deciding to take part in the study could have been an initial psychological crisis close to the start of the study, which resulted in hospitalisation and incapacity to work. The probability of such individuals having another comparably severe mental health crisis in the following year is less than 1 in both the intervention and control groups. Moreover, more individuals received regular psychological or psychotherapeutic care over time.

The adjusted health-care cost difference per participant between ImPuls plus TAU and TAU alone after 12 months was €–312 (95% CI –919 to 296). When intervention costs were included, the adjusted difference was €553 (–148 to 1255). Thus, ImPuls did not achieve overall cost savings from the SHI perspective. At the same time, we observed significant improvements in symptom severity and an incremental gain in QALYs at 12 months. In the base case analysis, the ICER and ICUR were €146 per BSI-18 point change and €17 543 per QALY, respectively. Per-protocol and complete case analyses produced ICUR estimates of €15 438 and €15 228 per QALY, respectively. Distributing within-trial costs over the number of intervention participants resulted in an ICUR estimate of €22 032 per QALY. This was mainly driven by allocating the training costs of the 20 exercise therapists just to the number of participants in the intervention group and not the expected number of individuals they treat in routine care (appendix p 3). Including the costs of a SCID led to an ICUR estimate of €24 068 per QALY. The SCID was a pre-trial screening tool administered by trained psychotherapists to participants of both the intervention and control groups. The sensitivity analysis illustrates the cost-effectiveness if the screening cost were included as a prerequisite of ImPuls and the corresponding costs were only added in the intervention group. Hence, conceptually, these costs do not reflect incremental costs, because SCIDs were conducted in all included participants. Standardised structural diagnostics are typically conducted in routine care in Germany—usually by the referring psychotherapist or psychiatrist—before any type of referral, and they are therefore not specific to ImPuls. To interpret the overall base case results, cost-per-QALY thresholds, commonly used to indicate societal willingness-to-pay for a year in full health, are informative, although no official threshold exists for Germany. Thresholds applied in the UK and the Netherlands, and empirical estimates for Germany,[25] suggest that interventions with ICURs between €20 000 and €40 000 per QALY can be considered cost-effective.[25] Against this benchmark, ImPuls plus TAU shows promise to be cost-effective from an SHI perspective.

This study adds to the scarce evidence on the costs and cost-effectiveness of exercise therapy for mental health conditions in outpatient care compared with standard treatment.[6] A UK trial including individuals with diagnosed depression found no benefit of a physical activity-related intervention on depression outcomes and reported higher costs (£220 after 12 months),[12] but it only included counselling and had the possibility of cross-treatment contamination.[27] Regarding exercise therapy, a Dutch study in people with major depressive disorder found no evidence that exercise therapy was effective or cost-effective, but the intervention adherence was only 22%.[11] More favourable results were reported in Sweden for people with mild to moderate depression, with an ICUR of €27 560 per QALY at 12 months from the health-care perspective (0·034 incremental QALYs at an approximate cost of €930), but the adherence to exercise was only 41%.[10] In comparison, the share of participants completing the minimum intervention dose in the ImPuls trial was 81%.[8] Additionally, differences in study populations and intervention formats limit comparability with our findings. To date, the cost-effectiveness of exercise interventions in a transdiagnostic population has not been examined. Demonstrating effectiveness and cost-effectiveness in a broader patient group has important implications for the design and implementation of future interventions. A group-based format that is open to people with diverse mental health conditions and delivered outside of psychotherapeutic care, with easy accessibility, could complement existing services and help offset the limited access to established treatments. In doing so, it might contribute to preventing symptoms being exacerbated and becoming chronic.

This study has several limitations. First, the ImPuls trial was conducted during the COVID-19 pandemic. In addition to general lockdown restrictions and contact limitations, reductions in the availability of mental health services[28,29] and increased levels of anxiety and depressive symptoms have been documented for Germany, especially for the period before the study.[30] It is unclear to what extent this limits the generalisability of the results of our study, but the baseline BSI-18 values in our sample were similar to the values reported in the German validation study of the BSI-18 in a clinical sample.[31] The pandemic could also have affected adherence to the intervention. Attendance of supervised sessions might have been lower due to fears of a COVID-19 infection, but given that exercise sessions took place outdoors and a high level of attendance was observed, this part of the intervention might not have

been considerably affected. Due to the pandemic, many supported and unsupervised group sessions had to be held online, which might have reduced their effect on longer-term physical activity adoption and the overall effects of the intervention. Second, the trial was carried out in Baden-Württemberg, an economically strong region with a comparatively high number of outpatient psychotherapists. It is unclear whether the efficacy of interventions such as ImPuls would be different in a context where fewer people receive psychotherapy in addition to an exercise intervention. Implementing and providing interventions such as ImPuls might be more difficult in more deprived regions with lower availability and spatial accessibility of centres for rehabilitation or exercise therapy. Third, given the type and context of our trial, we cannot rule out some degree of self-selection bias in our estimates, although many different instruments were used for participant recruitment. By excluding individuals with already high levels of physical activity from the trial (appendix p 25), the potential bias created by individuals with a higher affinity to physical activity self-selecting into the study was reduced.

Fourth, the health-care cost data were derived from claims submitted for billing purposes, which can be affected by coding practices and reimbursement rules. Fifth, the cost analysis was limited by low statistical power due to the extreme right skewness of the SHI cost data. Sixth, the SHI perspective of this analysis did not factor in other societal costs and effects, such as productivity costs beyond sick pay or spillover effects, as well as travel costs and opportunity costs of individuals. Seventh, we did not assess the sample with regard to its composition in relation to racial or ethnic groups. Finally, the intervention aimed to encourage sustained engagement in endurance-based physical activity, supported beyond the supervised phase by a smartphone application. Given this long-term behavioural focus, the potential for lasting quality-of-life improvements, and the preventive nature of ImPuls with respect to mental health crises and health-care use, the 12-month time horizon probably underestimates the cost-effectiveness of the intervention. Finally, people with lived experience were not involved in the study design, conduct, and reporting.

Overall, our findings indicate that implementing the ImPuls exercise intervention would not be cost saving from the SHI perspective but would generate benefits at a reasonable cost-effectiveness ratio that can be considered favourable after 12 months. With respect to integration into routine care, it is important to emphasise that the intervention was evaluated alongside TAU. Further research is needed to establish the optimal method of integration, whether as a standalone intervention or in combination with other treatments. Future studies should also include adequately powered subgroup analyses to explore different treatment pathways and patient populations. Detailed insights regarding implementation fidelity, adherence, contextual factors, and barriers and enablers to implementation were generated during the ImPuls trial in a mixed-method process evaluation, the results of which will be published elsewhere.[32] The promising cost-effectiveness results presented in our study provide valuable information to policy makers regarding the implementation of exercise-based interventions such as ImPuls in routine care.

Contributors

SW, A-LF, LZ, LS, ARM, GS, and TE contributed to the conception and the design of the study and acquisition of funding. SW was responsible for the administration of the entire ImPuls project. TE, LZ, A-LF, SP, GS, TE, and LS were responsible for project administration as consortium partners. SW and AKF were responsible for study organisation, recruitment, and assessment, training of the exercise therapists, and data management. ARM was responsible for the application design, development, and maintenance. SP was responsible for the recruitment of the study sites and the qualification of the exercise therapists. A-LF and LZ were the representatives of the two statutory health insurers, providing the routine data for the health economics analysis and supporting patient recruitment. EH, MMG, KT, TN, and TE were responsible for data management, data handling, the randomisation procedure, data preprocessing, and analysis of treatment fidelity. EH, MMG, TE, and TN verified the primary data, and had access to the raw study data. KT assisted in the specification of the imputation and analysis. SH and LS have accessed and verified the claims data, had access to both primary data and claims data, and conducted the health economic analysis. Original draft preparation was done by SH. All authors contributed to the drafting and revision of the final study protocol. SH and LS confirm responsibility for the decision to submit for publication.

Declaration of interests

SP declares that the German Association for Health–Enhancing Physical Activity and Exercise Therapy maintains a training programme for psychiatry, psychosomatics, and addiction. All other authors declare no competing interests.

Data sharing

Self-reported individual participant data that underlie the effectiveness results reported in this Article are available on the Open Science Framework (https://osf.io/5rcuz/files/6ve8z). Participants gave informed consent for their data to be published after de-identification (except for the routine and administrative data from the statutory health insurers). Routine and administrative data from the participating statutory health insurers underlying the cost and cost-effectiveness analysis will not be made available due to data privacy regulations. Analysis code for the main cost-effectiveness analysis reported in this paper will be posted on the Open Science Framework in the same repository.

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