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General psychiatric management for patients with personality disorder and/or self-harm behaviour

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[General Psychiatric Management för patienter med personlighetsstörning och/eller självskadebeteende]

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1. Abstract

Background

Personality disorder, specifically borderline personality disorder (BPD), is a prevalent mental health condition. The severity of the condition varies from mild to severe, and may include self-harm behaviour, including suicide attempts. Prevalence in Swedish clinical psychiatric populations is 10-40%. The condition is usually treated with manualised psychosocial treatment, of which General psychiatric management (GPM) is a more recently developed method. The method is specifically tailored for individuals diagnosed with BPD and comprises case management and a dynamically informed psychological treatment delivered in a group and/or individual format using a multi-professional approach.

Question at issue

In individuals with personality disorder and/or self-harm behaviour, are there any benefits and risks of treatment with GPM compared with any other intervention or no intervention concerning mortality, suicide/attempted suicide, self-harm, symptom remission, health-related quality of life, health care utilisation, disability/function, patient experience and complications?

Methods

Database searches were performed in January 2023. Titles and abstracts, and subsequently full text articles, were independently screened by at least two authors, and final inclusion was decided in consensus amongst all authors. Included studies were critically appraised, and data were extracted. For outcomes where comparative data were available, certainty of evidence was assessed using the GRADE approach.

Results

Four studies (n=386) evaluating GPM in individuals diagnosed with BPD, reported in nine publications, were included. One RCT (n=180) compared GPM with another active treatment (dialectical behaviour therapy: DBT, a manualised psychosocial treatment). No studies with other comparisons were identified. One non-RCT (n=96) compared GPM with no intervention (wait list). Two RCTs (n=110) compared two versions of GPM. Because the comparison was non-congruent with our PICO but the interventions in both trial arms corresponded to the intervention in our PICO, they were included as case series. The included studies had serious limitations and low to very low precision.

Mortality was evaluated in one RCT comparing GPM with DBT. No deaths related to the treatment were reported. It is uncertain whether there is any difference in mortality between GPM and other treatment methods (GRADE ⊕○○○).

Suicide attempts were evaluated in one RCT comparing GPM with DBT. There may be little or no difference in suicide attempts (GRADE ⊕⊕○○).

Self-harm was evaluated in one RCT comparing GPM with DBT. There may be little or no difference in number of self-harm episodes (GRADE ⊕⊕○○).

Symptom remission was evaluated in one RCT comparing GPM with DBT and one non-RCT comparing GPM with no intervention (wait list). There may be little or no difference between GPM and DBT regarding symptom severity, depression, anger expression, or symptom distress (GRADE ⊕⊕○○). There may be a greater symptom remission with GPM versus no treatment, with a large magnitude of effect (GRADE ⊕⊕○○).

Health-related quality of life was measured in one RCT comparing GPM with DBT. There may be little or no difference between GPM and DBT (GRADE ⊕⊕○○).

Healthcare utilisation was measured in one RCT comparing GPM and DBT. There may be little or no difference between GPM and DBT in healthcare utilisation (GRADE ⊕⊕○○).

Disability/function was measured in one RCT and in a case series extracted from RCT data. There may be little or no difference in functioning between GPM and DBT post-treatment or at 36 months (GRADE ⊕⊕○○). Functioning was significantly improved at 36 months within both groups (GRADE ⊕⊕○○).

Economic aspects

Costs estimated based on a 52-week treatment model as provided in the RCT were slightly lower for GPM; 41,000 SEK per patient compared to 50,000 SEK for usual care (DBT). GPM can also be delivered as brief individual and/or group-based treatment. In such scenarios treatment costs are estimated at 5,000–9,000 SEK/patient for 10 weeks' individual therapy and 900 SEK/patient for 6 weeks' group therapy. Hence, costs for GPM vary considerably due to different treatment length and the different staff categories involved in the treatment. Choice of treatment model is primarily influenced by the severity of the disease. Costs for usual care in VGR is estimated at approximately 55,000 SEK/patient.

Ethics

A lack of research in which adverse events or complications are reported precluded a proper benefit/risk assessment. Nevertheless, based on the included studies GPM may result in more patient benefits than no treatment and similar benefits compared with DBT. The large variation in BPD disease severity suggests a need for different treatment approaches, wherein a more generalist treatment approach such as GPM for patients with less or moderately severe BPD could potentially save resources for more intensive treatment of patients with greater disease severity.

Conclusion

Based on low certainties of evidence from primarily one RCT, there may be little or no difference between GPM and DBT in suicide attempts, self-harm behaviours, symptom remission, health-related quality of life, healthcare utilisation, and disability/function in patients with BPD. Based on low certainty of evidence from one non-RCT, there may be a greater symptom reduction in patients with BPD receiving GPM compared with no treatment (wait list).

2. Populärvetenskaplig sammanfattning – Plain language summary in Swedish

I denna rapport har vi utvärderat frågeställningen: Finns det någon nytta och risker med behandlingsmetoden ”General Psychiatric Management” (GPM) för patienter med personlighetsstörning och/eller självskadebeteende jämfört med andra behandlingar eller ingen behandling avseende dödlighet, självmord/självmordsförsök, självskador, symtomförbättring, hälsorelaterad livskvalitet, sjukvårdskonsumtion, funktion, patienterfarenheter och komplikationer?

Bakgrund

Personlighetsstörning, specifikt borderline personlighetssyndrom (BPD), är ett vanligt tillstånd av psykisk ohälsa som kan orsaka stort lidande för patienten. Förekomsten i Sverige inom psykiatri är cirka 10-40%. Tillståndet behandlas vanligen med manual-baserade behandlingsmetoder (psykoterapi), varav GPM är en nyare metod.

Metod

Databassökningar gjordes i januari 2023. Urval gjordes av minst två författare och projektgruppen beslöt gemensamt vilka artiklar som skulle inkluderas i rapporten. De ingående studiernas kvalitet granskades och data extraherades i tabeller (se bilagor). Resultatens tillförlitlighet bedömdes enligt GRADE för de utfall där jämförande data fanns tillgängliga.

Resultat

Rapporten är baserad på fyra studier med totalt 386 deltagare, med relevanta data presenterade i nio artiklar. Studierna hade allvarliga begränsningar i kvalitet (framför allt stort bortfall) och låg till mycket låg precision.

En randomiserad kontrollerad studie (n=180) jämförde GPM med en annan psykoteraeutisk behandling, dialektisk beteendeterapi (DBT) som är en kognitiv beteendeterapi baserad på en manual. En icke-randomiserad kontrollerad studie (n=96) jämförde GPM med en kontrollgrupp på väntelista för behandling med GPM efter studiens slut.

Två icke-randomiserade studier (n=110) jämförde GPM enbart med GPM kombinerat med en annan behandling och kunde därför bara ingå i rapporten som fallserier.

Dödlighet utvärderades i studien som jämförde GPM med DBT. Inga behandlingsrelaterade dödsfall inträffade under studieperioden. Det är osäkert huruvida det finns någon skillnad i dödlighet mellan GPM och andra behandlingsmetoder (GRADE ⊕○○○).

Självmordsförsök utvärderades också i studien som jämförde GPM med DBT. Antal självmordsförsök kan vara likvärdigt med de två behandlingarna och minskade i båda grupperna (GRADE ⊕⊕○○).

Självskadebeteende utvärderades också i studien som jämförde GPM med DBT. Antalet självskadeepisoder kan vara lika vanliga med de två behandlingarna och minskade i båda grupperna (GRADE ⊕⊕○○).

Symtomförbättring utvärderades i studien som jämförde GPM med DBT och i studien som jämförde GPM med ingen behandling (väntelista). Symtomförbättring mätt som symtomens svårighetsgrad, depression, uttryck för ilska eller symtomstress kan vara likvärdig med de två behandlingarna (GRADE ⊕⊕○○). Symtomförbättring kan vara större med GPM än med ingen behandling, med stor effektstorlek (GRADE ⊕⊕○○).

Hälsorelaterad livskvalitet utvärderades i studien som jämförde GPM med DBT. Hälsorelaterad livskvalitet kan vara likvärdig med GPM och DBT (GRADE ⊕⊕○○).

Sjukvårdskonsumtion utvärderades i studien som jämförde GPM med DBT. Sjukvårdskonsumtion kan vara likvärdig med GPM och DBT. Antalet akutmottagningsbesök och antal vård dagar i psykiatrisk vård kan minska med både GPM och DBT jämfört med före behandlingen (GRADE ⊕⊕○○).

Funktion utvärderades i studien som jämförde GPM med DBT och i fallserierna. Funktion kan vara likvärdig med GPM och DBT (GRADE ⊕⊕○○). Vid uppföljning två år efter behandling kan funktionen vara förbättrad med båda behandlingsmetoderna (GRADE ⊕⊕○○).

Ekonomiska aspekter

Kostnaden, uppskattad utifrån behandlingsupplägg på 52 veckor i den randomiserade studien, var något lägre för GPM; cirka 41000 SEK/patient jämfört med sedvanlig behandling, cirka 50000 SEK/ patient. GPM kan även erbjudas som en kort individuell och/eller gruppbaserad behandling, särskilt för patienter med mild till måttlig BPD, och behandlingkostnaderna uppskattas då till cirka 5000–9000 SEK/patient för 10 veckors individuell behandling respektive cirka 900 SEK/patient för 6 veckors gruppbehandling. Kostnaden för GPM varierar utifrån behandlingens längd och form samt vilka yrkeskategorier som är involverade. Val av behandlingsupplägg beror främst på tillståndets svårighetsgrad. Kostnaden för sedvanlig behandling i VGR uppskattas till cirka 55000 SEK/patient.

Etiska aspekter

Då det saknas rapporter om biverkningar eller komplikationer i de studier som har gjorts, kan inte en adekvat risk/nytta-bedömning göras. Dock tyder studierna som ingår i denna rapport på större patientnytta med GPM än ingen behandling, och likvärdig nytta som DBT. Den stora variationen i svårighetsgrad av BPD talar för ett behov av olika behandlingsmodeller, där en mer generell modell som GPM för patienter med mild till måttlig svårighetsgrad och utförd som kortare grupp- eller individuell terapi potentiellt kan frigöra resurser till mer intensiv behandling för patienter med högre svårighetsgrad.

Slutsatser

Baserat på en begränsad vetenskaplig litteratur med låg tillförlitlighet, kunde ingen skillnad ses mellan GPM och DBT gällande antal självmordsförsök, självska-debeteende, symtomremission, hälsorelaterad livskvalitet, sjukvårdsanvändning och funktion hos patienter med BPD. Jämfört med ingen behandling (stå kvar på väntelista) kan GPM dock resultera i en större symtomminskning.

The above summaries were written by representatives from the HTA-centrum. The HTA report was approved by the regional board for quality assurance of activity-based HTA. The abstract is a concise summary of the results of the systematic review. The plain language summary in Swedish is intended for decision makers.

Christina Bergh, Professor, MD

Head of HTA-centrum of Region Västra Götaland, Sweden, 24 November 2023

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MD Medical Doctor

PhD Doctor of Philosophy

OD Odontology Doctor

PT Physiotherapist

RN Registered Nurse

3. Summary of findings

Outcome	Study design, number of studies, number of participants	Absolute effect (GPM vs control)	Certainty of evidence, GRADE*
Mortality	1 RCT (n=180) (GPM vs DBT)	No deaths due to treatment reported in either group	⊕○○○ ¹
Suicide attempts	1 RCT (n=180) (3 publications) (GPM vs DBT)	<u>Number of suicide attempts, mean (SD)[†]</u> GPM / DBT Baseline: 1.9 (6.3) / 1.3 (3.6) Post-treatment (12 months): 0.3 (2.1) / 0.3 (1.3), ns [#] 24-month follow-up: 0.1 (0.3) / 0.1 (0.3), ns [#] 36-month follow-up: 0.3 (1.1) / 0.6 (2.4), ns [#]	⊕⊕○○ ²
Self-harm	1 RCT (n=180) (3 publications) (GPM vs DBT)	<u>Number of self-harm episodes, mean (SD)</u> GPM / DBT Baseline: 32.2 (81.9) / 21.0 (33.3) Post-treatment (12 months): 12.9 (51.4) / 4.3 (9.3), ns [#] <u>Severity of self-harm episodes, mean (SD)</u> GPM / DBT Baseline: 3.7 (2.6) / 4.3 (2.9) Post-treatment (12 months): 1.3 (2.0) / 1.7 (2.4), ns [#]	⊕⊕○○ ²
Symptom remission	1 RCT (n=180) (3 publications) (GPM vs DBT) 1 non-RCT (n=96) (GPM vs no treatment) 4 case series (n=110) (2 publications)	<u>BPD symptom severity (ZAN-BPD), mean (SD)</u> GPM / DBT Baseline: 14.9 (6.6) / 15.5 (6.1) Post-treatment (12 months): 8.2 (5.8) / 7.9 (6.1), ns [#] <u>BPD symptom severity (ZAN-BPD), mean (SD)</u> GPM / wait list Baseline: 22.0 (7.6) / 23.5 (6.2) Post-treatment (6 weeks): 12.3 (7.4) / 22.2 (7.1), p<0.001 [#] 8-week follow-up: 13.0 (7.8) / 20.1 (7.4), p<0.001 [#]	⊕⊕○○ ² ⊕⊕○○ ³

Health-related quality of life	1 RCT (n=180) (2 publications) (<i>GPM vs DBT</i>)	<u>EQ-5D, mean (SD)</u> GPM / DBT Baseline: 55.3 (19.4) / 57.7 (21.6) Post-treatment (12 months): 59.4 (22.0) / 63.8 (20.5), ns [#] 24-month follow-up: 63.2 (20.4) / 64.8 (21.6), ns [#] 36-month follow-up: 67.7 (21.0) / 64.3 (21.1), p=0.007 [#]	⊕⊕○○ ²
Healthcare utilisation	1 RCT (n=180) (2 publications) (<i>GPM vs DBT</i>)	<u>ED visits, mean (SD)</u> GPM / DBT Baseline: 2.1 (3.5) / 2.0 (3.0) Post-treatment (12 months): 1.0 (2.2) / 0.9 (1.5), ns [#] 36-month follow-up: 0.7 (1.2) / 0.7 (1.5), ns [#] <u>ED visits for suicidal behaviour, mean (SD)</u> GPM / DBT Baseline: 0.8 (1.6) / 1.0 (1.5) Post-treatment (12 months): 0.3 (1.1) / 0.4 (1.0), ns [#] 36-month follow-up: 0.2 (0.6) / 0.3 (1.2), ns [#] <u>Days in psychiatric hospital mean (SD)</u> GPM / DBT Baseline: 8.7 (24.9) / 10.5 (24.4) Post-treatment (12 months): 2.2 (6.6) / 3.7 (14.9), ns [#] 36-month follow-up: 3.0 (9.6) / 2.8 (13.3), ns [#]	⊕⊕○○ ²
Disability/function	1 RCT (n=180) (<i>GPM vs DBT</i>) 4 case series (n=110) (<i>GPM and GPM+MOTR</i>)	<u>Interpersonal functioning, IIP-64, total score mean (SD)</u> GPM / DBT Baseline: 121.0 (37.3) / 118.6 (43.8) Post-treatment (12 months): 101.6 (45.2) / 100.2 (50.6), ns [#] 36-month follow-up: 84.4 (45.5) / 94.5 (48.0), ns [#]	⊕⊕○○ ²

BPD: Borderline personality disorder; DBT: Dialectical behaviour therapy; ED: Emergency department; EQ-5D: Euroqol Health-related quality of life, 5 dimensions (scale 0-100, higher better); GPM: General psychiatric management; IIP total score: Inventory of interpersonal problems–64, total score. 64-items (higher scores indicate more interpersonal distress; MOTR: Motivation-oriented therapeutic relationship; non-RCT: Non-randomised controlled trial; ns: not significant; RCT: Randomised controlled trial; ZAN-BPD: Zanarini rating scale for borderline personality disorder (scale 0 to 36, higher worse)

Footnotes:

¹RCT downgraded one step for serious study limitations and some indirectness and two steps for very serious imprecision

²RCT downgraded one step for serious study limitations and one step for serious imprecision

³non-RCT, starting at low certainty of evidence, downgraded one step for some study limitations and upgraded one step for large magnitude of effect

†All numbers rounded off to one decimal

Indicates difference between treatment groups at follow-up visits.

*Certainty of evidence assessed based on the RCT, according to the below definitions:

High certainty ⊕⊕⊕⊕	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty ⊕⊕⊕○	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty ⊕⊕○○	Confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low certainty ⊕○○○	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

4. Abbreviations/Acronyms

BPD = Borderline personality disorder
CM = Conventional methods
DBT = Dialectical behaviour therapy
GPM = General/Good psychiatric management
ICD = International classification of diseases
MBT = Mentalization-based therapy
MOTR = Motive-oriented therapeutic relationship
Non-RCT = Non-randomised controlled trial
NR = Not reported
ns = Not significant
PD = Personality disorder
RCT = Randomised controlled trial
UC = Usual care
VGR = Region Västra Götaland

5. Background

Disease/disorder of interest and its degree of severity

Personality disorder (PD) is defined as a marked disturbance in personality functioning that is nearly always associated with considerable personal and social disruption, as well as significant suffering for the individual. Central to this disorder are impairments in aspects of self-functioning, such as identity, self-worth, and capacity for self-direction, and/or problems in interpersonal functioning, which include difficulties in developing and maintaining close and mutually satisfying relationships, understanding others' perspectives, and managing conflict in relationships (International Classification of Diseases [ICD-11]). Despite numerous variants of PDs, a majority of the research has focused on a specific subgroup of patients with PD: those who meet the diagnostic criteria for borderline personality disorder (BPD) (Bateman et al., 2015).

Borderline personality disorder, also referred to as emotionally unstable personality disorder in the forthcoming ICD-11, is distinguished by persistent and marked instability in interpersonal relationships, self-perception, emotional response, and impulsivity (American Psychiatric Association [APA], 2013). Self-destructive behaviour patterns, including self-harm and multiple comorbidities such as substance abuse and posttraumatic stress disorder are commonly observed among individuals diagnosed with BPD. Similar to other personality disorders, BPD can significantly impact functionality, physical health, and overall quality of life (Skodol et al., 2002, El-Gabalawy et al., 2010). Estimates of suicide rates among individuals with BPD vary, with some studies suggesting a rate of 3% while others propose rates as high as 10% (Paris, 2019).

The etiology of BPD remains uncertain; however, it is posited that this disorder arises from a complex interplay between genetic predisposition and environmental factors (Wilson et al., 2021; Linehan, 2014). A substantial portion of individuals with BPD report histories of neglect and varying degrees of trauma (Silk et al., 2005). Socioeconomic determinants may also contribute, with higher prevalence rates noted in societies characterised by higher degrees of individualisation, urbanisation, social fragmentation, and inequality (Karterud et al., 2014). Neuroimaging studies of adults with BPD have shown abnormalities within the amygdala, hippocampus, and prefrontal regions, critical areas involved in emotional regulation, impulse control, and social stimulus interpretation (van Zutphen et al., 2015).

Not all individuals who practice self-harm meet the diagnostic criteria for BPD and not all individuals with BPD practice self-harm (Sansone et al., 2005).

Self-harm is a broad term that encompasses intentional, self-directed damage to oneself either with or without suicidal intent, whereas non-suicidal self-injury refers to non-lethal self-harm that does not include suicidality (APA, 2013). The former term, self-harm, is used by the National Institute for Health and Care Excellence in their quality standards (NICE, 2013) and historically within Sweden's national self-harm project (Nationella självskadeprojektet, 2016). There may be difficulties in using non-suicidal intent as a defining factor in self-harm behaviour, since intention may change over time, learning and habituation (APA, 2013). A large multi-center study has identified self-harm as the most central contributor to death by suicide (Hawton et al., 2015), supported by other research proposing that even non-suicidal self-injury is associated with later death by suicide (Wilkinson, 2011). As such, suicide and self-harm are related and at times overlapping constructs.

Self-harm encompasses numerous behaviours that range in directness and lethality, which may be conceptualised across these spectra (Liljedahl et al., 2023).

Prevalence and incidence

The epidemiology of personality disorders is less well-defined compared to other mental disorders, partly due to the challenges of obtaining accurate personality assessments in national surveys. Cross-sectional, community-based surveys in North America and western Europe report a point prevalence of personality disorders between 4% and 15%. The prevalence of personality disorder is significantly higher among individuals in contact with healthcare services; approximately a quarter of primary care patients and 50% of psychiatric outpatient clients meet the criteria for the disorder. Moreover, two-thirds of individuals in contact with the criminal justice system have a personality disorder (Tyrer et al., 2015).

Regarding BPD, population-based studies report a point prevalence of around 1% in the general population (Ellison et al., 2018). In clinical settings, the prevalence is substantially higher, with around 12% in the outpatient psychiatric population and 22% among inpatients). In Sweden, prevalence of BPD in clinical population is reported at about four percent within primary care, 10-20% within psychiatric outpatient care, and 20-40% within psychiatric inpatient care (Region Stockholm, 2023). Seventy-five percent of patients with BPD are women.

With respect to the incidence and prevalence of self-harm nationally and internationally, reliable estimates amongst adults have been difficult to determine due to differing classification systems. If adhered to stringently by clinicians, the self-harm coding system in the forthcoming ICD-11 has much potential for researchers generating epidemiological data (ICD-11).

Present treatment

No medications are approved for the treatment of personality disorder but are usually employed to treat comorbidity and to alleviate the most severe symptoms (Shapiro-Thompson and Fineberg, 2022). There are a number of manualised psychosocial treatments available, primarily for BPD, with varying levels of evidence (Rao et al., 2020). The most studied among these therapies are Mentalization-based therapy (MBT) and Dialectical behaviour therapy (DBT). These treatments typically last for 1-2 years and combine one individual and one group session per week. Both treatments can be administered by various professional groups within psychiatry with competence in psychotherapy, but they require specific additional training for each method.

For self-harm, there are increasing psychological treatment options. Psychosocial treatments such as DBT and MBT, originally developed to treat BPD in which repeated self-harm may occur, can reduce the frequency of self-harm (Stoffers-Winterling et al., 2022). However, evidence for the efficacy of those therapies in self-harm alone is still developing (Witt et al., 2021b). Additionally, a number of so-called add-on treatments, such as Manual assisted cognitive treatment, DBT skills training, and Emotion regulation group therapy, have been developed to treat BPD patients with self-harm. In Sweden, both DBT skills training and Emotion regulation group therapy are practiced. While both treatments have shown promise in addressing key aspects of BPD, their effectiveness specifically for self-harm remains uncertain (Stoffers-Winterling et al., 2022).

Medications are recommended to treat underlying comorbidity when present, but guidelines advise against prescribing medications to treat self-harm (Witt et al., 2021a).

Standard pathway through the healthcare system and current wait time for medical assessment/treatment

The first access to psychiatric care for an individual with BPD is usually through primary care. Primary care offers basic medical treatment, including first-step pharmacological and psychological interventions for several psychiatric conditions. Primary care can refer patients to specialised care if needed. Waiting list to first assessment in psychiatric clinics is regulated by the so-called Healthcare guarantee (Vårdgaranti) and limited to three months. More commonly, patients with BPD came to observation through emergency departments following episodes of crisis, self-harm and/or suicidal attempt. In Region Västra Götaland (VGR) the Healthcare guarantee for patients suffering from BPD has been in place since 2008. No data are available regarding self-harm. The first contact in specialised care involves a personality assessment to provide insight to both the patient and the healthcare professional about the severity of the disorder, the personality traits pattern, and the individual's needs. Psychoeducation is recommended at an early stage to promote compliance and treatment alliance. A psychiatric evaluation is performed to assess the indication for pharmacotherapy, followed by the development of a safety plan to manage crises. Waiting time between the assessment and treatment varies depending on the specialised clinic (and the region in question), type of treatment and year, but is estimated to 3-6 months.

Number of patients per year who undergo current treatment regimen

In 2022, a total of 3,991 patients with an F60 diagnosis (specific personality disorders) were treated in VGR, of which 1481 patients were treated at Sahlgrenska University Hospital (Vega/Regional vårdanalys). Of the 3,991 patients, 2,432 patients (60.9%) had the diagnosis F603 (emotionally instable personality disorder). In total, 40,451 visits (physical and digital) were registered for patients with an F60 diagnosis, of which 26,747 were for patients with F603.

Number of visits for a personality disorder (F60) by healthcare professional category in 2022 is shown in Figure 1.

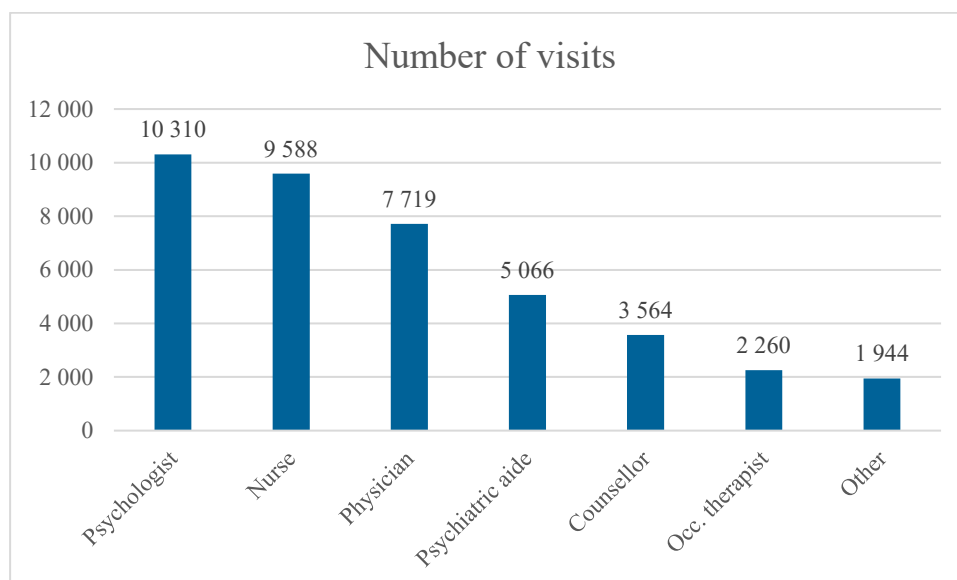


Figure 1. Number of visits by healthcare professional category. Source: Vega/Regional vårdanalys

Number of patients with F60 diagnosis and number of visits by type of treatment in 2022 are shown in Table 1. Only the top 12 types of treatment are shown.

Table 1. Number of patients with F60 diagnosis and number of visits by type of intervention (KVÅ code)

Type of intervention	No. of patients	No. of visits
Dialectical Behaviour Therapy (DU021)	335	5,700
Mentalisation-Based Therapy (DU013)	182	3,912
Counselling (DU112)	718	3,303
Structured suicide risk assessment (AU118)	1 045	2,728
Telemedicin (i) (ZV051)	774	2,215
Psychodynamic therapy (DU008)	152	1,881
Psychoeducation (DU023)	242	1,408
Information and education targeting patient (GB009)	251	1,367
Other specified psychologic treatment (DU009)	209	1,297
Psychodiagnostic assessment (AU009)	785	1,268
Cognitive Behaviour Therapy (DU011)	179	1,156

Source: Vega/Regional vårdanalys

No data were registered in the Vega database for the Z diagnoses for suicide attempts or self-harm behaviours.

Present recommendations from medical societies or health authorities

Amongst the first to be published in Europe and recently revised, the clinical guidelines for treatment of personality disorders, by the Swedish Psychiatric Association, are well updated and mainly focused on applicability (Svenska psykiatriska föreningen [SPF], 2017). In line with other European guidelines, psychosocial intervention is recommended as the primary treatment for borderline personality disorder and other personality disorders, principally DBT and MBT (Simonsen et al., 2019). The guideline discourages both pharmacological treatment of personality disorder core symptoms and polypharmacy but justifies medications as an addition to other treatments for symptom relief and in case of severe crisis. Treatment with addictive drugs as benzodiazepines should be avoided. Region Västra Götaland's regional medical and administrative guideline for self-harm behaviour amongst children and youth recommends commencing treatment of self-harm behaviour with assessment of disease severity, risk factors and protective factors and assessing emotional instability using a structured diagnostic interview such as SCID-II (First et al., 1997, Västra Götalandsregionen [VGR], 2023). The guideline underscores the importance of a non-judgmental attitude and of building a trusting relationship with the patient. For youth with self-harm behaviour, trust, continuity, and follow-up are extra important. There is no regional guideline for adults, however the VGR's national specialised self-harm medical unit follows Sweden's national recommendations for the treatment of self-harm (Nationella självskadeprojektet, 2016).

As first-line treatment, interventions recommended for self-harm behaviours are those stated in the National care program (Sveriges kommuner och regioner [SKR], no date). Recommendations include severity assessment and level-of-care allocations, preventive and supportive intervention in different context (school, social services, family), treatment planning, and aftercare. Treatment recommendations are generally relegated to evidence-based psychotherapies, the type of which may be influenced by what is available in the region.

Recently, the National Board of Health and Welfare (Socialstyrelsen) published guidelines for brief admission by self-referral (Socialstyrelsen, 2023), a form of agreement between patient and the

healthcare system that allows the patient to hospitalise themselves in case of need. Self-referral is implemented in 18 of 21 regions in Sweden. Originally developed for individuals with three or more symptoms of BPD and recurrent self-harm, the intervention is now aimed at patients with a recurrent need for inpatient care where access to alternative interventions is limited, and sometimes even non-existent. The effectiveness of self-referral in reducing self-harm or health care costs is still uncertain (Socialstyrelsen, 2021).

6. Health technology at issue: General Psychiatric Management

Despite a number of different treatments for BPD, current treatment approaches do not adequately meet the healthcare needs of the patient group (Gunderson and Links, 2014, Bateman and Krawitz, 2013). Factors such as the treatments' length, intensity, and the specialised expertise required of therapists hinder their broad implementation and make it challenging to provide quality care within a reasonable timeframe (Iliakis et al., 2019, Choi-Kain and Gunderson, 2019), and emphasising the need for less intensive and less resource-consuming treatment models that can serve as a complement to highly specialised treatments.

One such model is General psychiatric management (GPM) (Gunderson and Links, 2014), a therapeutic model formulated by the late American psychiatrist John Gunderson. Its development is anchored to the American Psychiatric Association's treatment guidelines for BPD and builds on Gunderson's earlier work (2001). The model was first formalised as a treatment model during its use as a control intervention in a 2009 study on DBT (McMain et al., 2009). The positive outcomes yielded by GPM in that study subsequently contributed to its recognition as a standalone treatment model, and the first treatment manual was published in 2015 (Gunderson and Links, 2014).

Characterised by its diverse nature, GPM incorporates techniques from other efficacious treatment models, including but not limited to DBT and MBT, as well as Transference focused psychotherapy. The underlying premise of GPM rests on the notion that BPD primarily stems from a partly inherent hypersensitivity to interpersonal dynamics. The primary aim of this treatment approach is to facilitate the patient's ability to manage this hypersensitivity within the safety of a therapeutic relationship. Core components of the original GPM model were case management, dynamically informed psychotherapy, and symptom-targeted medication management (McMain et al., 2009). Since its inception, the model has evolved to be adaptable across various contexts and interactions, without necessitating extensive training or prior experience with this patient group. In its present form, GPM is designed to serve not only as psychotherapy but also as a framework and support for other types of interactions with patients suffering from BPD (see, for example, Choi-Kain and Gunderson, 2019).

Central to the model are key principles that, when paired with an understanding of interpersonal hypersensitivity, direct the intervention process. These principles guide clinicians in providing a relationship that is not only supportive and secure, but also encourages challenge and responsibility. Furthermore, the principles are designed to be mindful of and responsive to the specific needs of the patient population. The treatment plan usually consists of 10 to 50 1-hour weekly sessions. The frequency of visits and the duration of therapy is not defined in advance but depends on treatment outcome, thus whether the therapy proves useful. Since GPM was developed as a generalist method, as opposed to specialised treatment methods such as MBT and DBT, it can be administered by any health care provider. It can be delivered as a group treatment, individual treatments, or a combination of both. Moreover, GPM encourages a multi-professional approach, so called "split treatment", where several professionals (usually a physician and a therapist) with different competences provide treatment at the same time.

7. Focused question

In patients with personality disorder and/or self-harm behaviour, are there any benefits and risks of treatment with General/Good Psychiatric Management as a stand-alone or adjunct treatment, compared with any other intervention or no intervention in terms of mortality, suicide/attempted suicide, self-harm, symptom remission, complications, health care utilisation, disability/function and patient experience?

PICO: P= Patients, I= Intervention, C= Comparison, O=Outcome

P	Patients with personality disorder and/or self-harm behaviour
I	General Psychiatric Management/Good Psychiatric Management as a stand-alone or adjunct treatment
C	Any other intervention or no intervention
O	<p><u>Critical for decision-making</u></p> <p>Mortality</p> <p>Suicide/attempted suicide</p> <p>Self-harm</p> <p>Symptom remission</p> <p>Health-related quality of life</p> <p><u>Important for decision-making</u></p> <p>Healthcare utilisation</p> <p>Disability/function</p> <p>Patient experience</p> <p>Complications</p>

Eligible study types: systematic reviews, RCTs, non-randomised controlled studies (non-RCTs), case series with at least 5 patients, qualitative studies

Languages: English, Swedish, Danish, Norwegian

If possible, subgroup analyses will be performed for different types of personality disorder, self-harm behaviour, and for comorbidity.

Relevance of the outcomes from a patient perspective was confirmed by a patient representative.

8. Methods

Systematic literature search (Appendix 1)

During January 2023 two authors (IS, AL) performed systematic searches in Medline (Ovid), Embase (Ovid), the Cochrane Library (Wiley) and PsycINFO (Ebsco). The websites of the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) and the Norwegian Institute of Public Health (Folkehelseinstituttet) were visited. Reference lists of relevant articles were also scrutinised for additional references. Search strategies, eligibility criteria and a graphic presentation of the selection process are presented in Appendix 1. These authors conducted the literature searches, selected studies, and independently of one another assessed the obtained abstracts and made a first selection of full-text articles for inclusion or exclusion. Any disagreements were resolved by consensus. The remaining articles were sent to all authors. All authors read these articles independently of one another and it was finally decided in a consensus meeting which articles should be included in the assessment.

The HTA was registered on PROSPERO on 5 March 2023 (registration code CRD42023402059), prior to data extraction.

Critical appraisal and certainty of evidence

The included studies and their design as well as patient characteristics are presented in Appendix 2. Data were extracted by one author and controlled by at least one more author. Excluded studies are listed in Appendix 3. Included studies were critically appraised using appropriate checklists from the SBU modified by HTA-centrum. Depending on study design, the checklist for randomised controlled trials, non-randomised controlled trials, or case series was used. In Appendices 4.1 through 4.7 the results and the risk of bias of each study are presented per outcome. Results per outcome and the associated certainty of evidence are summarised in a Summary-of-findings table (page 9). Certainty of evidence was assessed according to GRADE (Atkins et al., 2004), based on data from RCTs with relevant comparisons according to the predefined PICO.

Ongoing research

A search in Clinicaltrials.gov (13 March 2023) using the search term (“General psychiatric management” OR “Good psychiatric management”) identified three trials. A search in the WHO International Clinical Trials Registry Platform (13 March 2023) using the search terms (“General psychiatric management” OR “Good psychiatric management”) identified one trial. In total three unique ongoing trials were identified.

9. Results

Search results and study selection (Appendix 1)

The literature search identified 91 records after removal of duplicates. After reading the abstracts 66 records were excluded. Five additional reports were excluded (by two authors) after reading the articles in full text. The remaining 20 reports were sent to all authors and nine publications were finally included in the assessment (Appendix 2).

Included studies

Four studies, with a total of 386 patients, reported in nine publications, were included. All studies were conducted among patients with BPD. No studies were identified on GPM for patients with other personality disorders or with self-harm behaviour.

One Canadian RCT (n=180) (McMain et al., 2009, 2014) compared GPM with another active treatment (DBT). One Italian non-RCT (n=96) (Ridolfi et al., (2020) compared GPM with no intervention (wait list). Two Swiss RCTs (n=110), conducted by the same research group, evaluated a GPM as a stand-alone in one trial arm versus GPM combined with and adjunct treatment (motive-oriented therapeutic relation (MOTR), in the other trial arm (Kramer et al., 2011, Kramer et al., 2014). Since this comparison was non-congruent with the PICO of the current HTA, each trial arm was handled as a case series (reported here as four separate case series). In all studies, GPM was delivered as individual treatment.

Directness of the RCTs was assessed as satisfactory. In the case series, there were some problems with directness, due to participants being recruited from only one centre and unclear reporting of the recruitment strategies. The RCT by McMain et al. (2009) was assessed as having serious study limitations due to lack of blinding, high attrition rate, and many of the outcomes being self-reported. The non-RCT comparing GPM with no intervention (waitlist), by Ridolfi et al. (2020) also had serious study limitations due to lack of blinding and inadequate handling of statistical uncertainty. The two RCTs by Kramer et al. (2011, 2014) were assessed as having serious study limitations due to unclear reporting of recruitment, and outcome assessors not being blinded. The cases series (Berthoud et al., 2017, Maillard et al., 2017, Maillard et al., 2020) had serious study limitations: mainly insufficient length of follow-up, lack of assessor blinding, and lack of adverse events reporting. Precision was generally assessed as low due to wide or non-reported confidence intervals (McMain et al., 2012) and/or small sample sizes (Kramer et al., 2011, Kramer et al., 2014, Berthoud et al., 2017, Maillard et al., 2017, Maillard et al., 2020). For mortality, precision was assessed as very low due to very few events.

Results per outcome

Outcomes critical for decision-making

Mortality (Appendix 4.1)

Mortality was reported in one RCT (n=180) comparing GPM with DBT over 12 months for patients with BPD (McMain et al., 2009), and followed up two years after end of treatment (McMain et al., 2012). The study had serious study limitations, some problems with directness, and very serious imprecision regarding mortality due to no or very few events. At 12 months, there were no deaths in either group. At the 2-year follow-up, there were two deaths in the DBT group, but they were from natural causes.

Conclusion: It is uncertain whether there is any difference in mortality amongst patients with BPD treated with GPM compared with those treated with DBT (GRADE ⊕○○○).

Suicide attempts (Appendix 4.2)

Frequencies of suicide attempts were reported in one RCT (n=180) comparing GPM with DBT (McMain et al., 2009, McMain et al., 2012), and in a secondary analysis of the same trial (Boritz et al., 2016).

There were no significant differences in number of suicide attempts between the groups during the 12-month treatment period (baseline, GPM, mean [SD] 1.9 [6.3] vs. DBT 1.3 [3.6], and 12 months, GPM: 0.3 [2.1], vs. DBT: 0.3 [1.3], ns). The reduction in mean number of suicide attempts from baseline to end of treatment was significant in both groups ($p < 0.01$). There were no significant differences between GPM and DBT at any follow-up point (24 months, GPM, mean [SD]: 0.1 [0.3], and 36 months: 0.3 [1.2], vs. DBT, 24 months, DBT: 0.1 [0.3], ns., and 36 months: 0.6 [2.4], ns). Both groups maintained the reduced rate of suicide attempts observed during the treatment phase into the follow-up period.

There were no significant differences in the frequency of suicide attempts between patients with versus without PTSD comorbidity.

Conclusion: There may be little or no difference in the frequency of suicide attempts amongst patients with BPD treated with GPM compared with those treated with DBT (GRADE ⊕⊕○○).

Self-harm (Appendix 4.3)

Frequency and severity of non-suicidal self-harm episodes were assessed in one RCT (n=180), (McMain et al., 2009, McMain et al., 2012), with the impact of PTSD comorbidity reported in a secondary analysis by Boritz et al. (2016). There were no significant differences in the number of self-harm episodes between GPM and DBT (baseline GPM, mean [SD]: 32.2 [81.9], and 12 months: 12.9 [51.5]; baseline DBT: 20.9 [33.3], and 12 months: mean 4.3 [9.3], ns.), but significant *within-group* reductions were seen ($p < 0.001$). During follow up to 36-months there were no significant differences between GPM and DBT, at any time point.

There were no significant differences in non-suicidal self-injury frequency between patients with versus without PTSD comorbidity at end of treatment or follow-ups.

Conclusion: There may be little or no difference in self-harm behaviours amongst patients with BPD receiving GPM compared with DBT (GRADE ⊕⊕○○).

Symptom remission (Appendix 4.4)

Symptom remission was reported in one RCT (McMain et al., 2009, McMain et al., 2012) comparing GPM with DBT, one non-RCT (Ridolfi et al., 2020) comparing GPM with no intervention, and the two studies by Kramer et al. (2011, 2014) which in this HTA are treated as case series. The RCT had serious study limitations and serious imprecision, the non-RCT had some study limitations and serious imprecision and showed large effect post-treatment and very large effect at eight weeks' follow-up. The case series had some study limitations and very low precision.

BPD symptom severity was evaluated in two studies (McMain et al., 2009 and Ridolfi et al., 2020). using the Zanarini Rating Scale for Borderline Personality Disorder (ZAN-BPD). There were no significant differences in BPD symptom severity between GPM and DBT, measured as mean ZAN-BPD total score (baseline, GPM, mean [SD]: 14.9 [6.6], and 12-months: 8.2 [5.8]; baseline DBT: 15.5 [6.1], and 12-months: 7.9 [6.1], ns.), but significant reductions were seen *within* each treatment group over the course of treatment (time effect $p < 0.001$).

The non-RCT by Ridolfi et al. (2020) (n=96) showed a significantly greater reduction in the ZAN-BPD score in the GPM group compared with the wait-list group (baseline, GPM, mean [SD]: 22.0 [7.6], and 8-weeks 13.0 [7.8]; vs. baseline, DBT: 23.5 [6.2], and 8-weeks: 20.1 [7.4], $p < 0.001$).

Depression severity was assessed in the RCT using the Beck Depression Inventory (BDI). No significant differences in depression severity were seen between GPM and DBT (baseline, GPM, mean [SD]: 35.4 [10.6], and discharge: 24.8 [14.8]; baseline, DBT, 37.2 [12.5], and discharge: 22.2 [16.1], ns), but significant *within-group* reductions were seen for both groups ($p < 0.001$).

Anger expression was measured in the RCT using the STAXI anger expression subscore. No significant differences in depression severity were seen between GPM and DBT (baseline, GPM, mean [SD]: 17.6 [5.5], and 12-months: 16.0 [5.1]; baseline, DBT: 17.9 [5.3], and 12-months: 15.8 [5.2], ns.), but significant *within-group* differences were seen in both groups, $p = 0.004$).

Symptom distress was measured in the RCT using SCL-90. There were no significant differences between GPM and DBT (baseline, GPM, mean [SD]: 1.9 [0.86], and discharge: 1.4 [0.8]; baseline, DBT: 1.9 [0.8], and discharge: 1.4 [0.9], ns.), but both treatment groups reported significant *within-group* reductions in symptom distress, $p = 0.001$).

There was significantly greater improvement in BPD symptoms with DBT than with GPM, for those patients that did not have PTSD comorbidity ($Z = 2.25$, $p = 0.024$ (95% CI 0.024 to 0.356)).

In the pilot study by Kramer et al. (2011), a 10-session treatment with a variant of GPM with plan analysis alone was compared with GPM+MOTR for patients with BPD. Therapeutic outcome measured with the Outcome questionnaire (OQ-45.2) showed no overall effect between baseline and discharge ($F(1, 23) = 1.28$, ns).

The complete study (Kramer et al., 2014) suggested a reduction of global symptomatology as measured by the OQ-45.2, and the BSL-23: OQ-45 total at baseline (SD): 94.5 (26.4) vs discharge: 86.1 (25.4), p -value NR, and BSL-23 at baseline: 1.7 (0.9) vs discharge: 1.5 (1.0), p -value NR).

Conclusion: Based on low certainty of evidence, there may be little or no difference in symptom remission in patients with BPD receiving GPM compared with DBT (GRADE $\oplus\oplus\circ\circ$). Based on low certainty of evidence from one non-RCT, there may be a greater symptom reduction in patients with BPD receiving GPM compared with no treatment (GRADE $\oplus\oplus\circ\circ$).

Health-related quality of life (Appendix 4.5)

Health-related quality of life was reported in one RCT comparing GPM with DBT (McMain et al., 2009, McMain et al., 2012). The outcome was evaluated using the EQ-5D during a 12-month treatment period, without significant differences between the groups (baseline, GPM, mean [SD]: 55.3 [19.4], and 12 months: 59.4 [22.0], ns.; baseline, DBT: 57.7 [21.6], and 12 months: 63.8 [20.5], ns.). At 36-month follow-up, significant *within-group* improvements in health-related quality of life were seen (GPM mean [SD]: 67.7 [21.0]; DBT: 64.3 [21.1], $p = 0.007$).

Conclusion: There may be little or no difference in health-related quality of life amongst patients with BPD receiving GPM compared with DBT (GRADE $\oplus\oplus\circ\circ$).

Outcomes, important for decision-making

Healthcare utilisation (Appendix 4.6)

Healthcare utilisation was reported in one RCT comparing GPM with DBT (McMain et al., 2009, McMain et al., 2012). During the 12 months' treatment period, there were no significant differences between the GPM and DBT in the frequency of visits to the emergency department (ED) in general (baseline GPM, mean [SD]: 2.1 [3.5], and 12 months: 1.0 [2.2] vs. baseline DBT: 2.0 [3.0], and 12 months: 0.9 [1.5], ns); nor in ED visits for suicidal behaviour (baseline, GPM, mean [SD]: 0.8 [1.7], and 12 months: 0.3 [1.1] vs. baseline DBT: 1.0 [1.5], and 12 months: 0.4 [1.0], ns.), nor in days of psychiatric hospitalisation (baseline, GPM, mean [SD]: 8.7 [24.9], and 12 months: 2.2 [6.6] vs. baseline DBT: 10.5 [24.4], and 12 months: 3.7 [14.9], ns.). Significant *within-group* reductions during the treatment period were reported in both groups in all measures ($p < 0.001$). At the 36 months follow-up no significant differences were seen between or within the groups.

No significant differences were seen between GPM and DBT in number of psychosocial treatments (baseline GPM, mean [SD]: 1.5 [1.2], and 12 months: 0.6 [0.7]; baseline DBT: 1.5 [1.4], and 12 months: 0.3 [0.8], ns.), but significant *within-group* differences were seen ($p = 0.001$).

Conclusion: There may be little or no difference in healthcare utilisation amongst patients with BPD receiving GPM compared with DBT (GRADE ⊕⊕○○).

Disability/function (Appendix 4.7)

Disability/function was reported in one RCT comparing GPM with DBT (McMain et al., 2009, McMain et al., 2012), and in one RCT comparing GPM with GPM+MOTR (Kramer et al., 2014), here treated as two separate case series.

In both studies, disability/function was evaluated using the total score of the Inventory of Interpersonal Problems (IIP-64, total score). There were no significant differences between GPM and DBT at any time point (baseline, GPM, mean [SD]: 120.9 [37.3], and 12 months: 101.6 [45.2]; baseline DBT: 118.6 [43.8], 12 months: 100.2 [50.6], ns.) but significant *within-group* changes were seen at 12 months ($p < 0.001$). There were no significant differences between GPM and DBT regarding IIP-64 total scores at 36 months (GPM, mean [SD]: 84.4 [45.5]; DBT: 94.5 [48.0], ns.), but significant *within-group* changes were seen $p < 0.0001$.

Kramer et al. (2014) reported IIP total scores for the GPM group (baseline, mean [SD]: 1.7 [0.5], and at 10 weeks: 1.5 [0.7], ns), and for the GPM+MOTR group (baseline, mean [SD]: 1.9 [0.6], and at 10 weeks: 1.6 [0.6], ns).

Conclusion: There may be little or no difference in interpersonal disability amongst patients with BPD receiving GPM compared with DBT (GRADE ⊕⊕○○).

Patient experience

No study was identified that reported this outcome.

Complications

This outcome was not reported in any of the included studies.

10. Organisational aspects

Time frame for the putative introduction of the new health technology

The time frame for a putative introduction of GPM in VGR is 12 to 36 months. The training program for GPM consists of one day formal training, which can be provided in meetings or through an online course by Mclean Hospital, Harvard University. In line with GPM implementation guidelines, a group of core providers need training in person with a certified GPM trainer. Other professionals, identified as potential providers of the new method, could receive access to the online course. Core providers would be part of a GPM network providing support and coordination to the others. It is important to point out that GPM is not intended as a substitute to DBT or other more comprehensive treatment strategies but could be considered as an option to tailor treatment efforts to individual needs. In specialised psychiatry, GPM could be implemented so that it does not affect other treatment for personality disorders. The treatment could also be implemented in other psychiatric units not dedicated to treatment of personality disorders, such as psychiatric in-patient services, psychiatric emergency service, and general psychiatry out-patient services, as well as in primary care where mild personality disorder is managed.

Present use of the technology in other hospitals in Region Västra Götaland and Sweden

In VGR, GPM is not carried out on a routine basis in any of the major hospitals, but is provided by several healthcare professionals at individual level.

At the Personality Disorder Program at Psykiatri Sydväst in Stockholm, GPM is used as a treatment method for all forms of personality disorders (not solely for BPD). Depending on the patient's needs, the GPM treatment can vary in both duration and intensity, ranging from a 10-session structure comprised of assessment and psychoeducation, up to a maximum of 12 months of therapy (individual sessions with or without group sessions).

In Region Skåne, a pragmatic implementation study conducted in 2020 at a clinic not specialised in BPD treatment evaluated both patients' and clinicians' experiences with GPM and showed promising results (Ydrefelt, 2021). Based on these positive findings, the region is now advancing with the deployment of GPM across various healthcare settings, including outpatient psychiatry, day hospital psychiatric services, and addiction treatment services. As in Stockholm, GPM is used in the treatment of not just BPD, but in personality disorders in general. Additionally, primary care professionals within the region have been trained in the GPM approach.

Consequences of the new health technology for personnel

One possible consequence of GPM if provided as a group- or brief individual therapy would be increased availability and shorter waiting time to treatment in both primary and specialised care. On the other hand, due to limited resources, implementation of GPM might reduce availability to other treatment options. A possible solution could be to initially provide GPM training to personnel not usually engaged in other treatments – such as personnel at psychiatric in-patient services, psychiatric emergency services or primary care as well as physicians and nurses in psychiatric out-patient services.

Consequences for other clinics or supporting functions at the hospital or in the Region Västra Götaland

No significant consequences for other clinics or departments are expected. The introduction of GPM might nonetheless require reallocation of resources, such as training staff and funding. The transition to a new method often influences common treatment strategies and might result in conflict in treatment philosophies. As the treatment options shift there might be a change in patient referrals, e.g., patients that do not fit treatments as usual, which in turn might affect collaboration and communication between departments. Changes in patient volume and complexity might also affect staff workload. The impact of GPM on comorbid conditions (e.g. substance abuse, depression, bipolar disorder) is still unknown and might potentially alter the treatment strategies with unclear results on outcome. On the other end, the effectiveness of GPM outside specialised care for PD might influence treatment strategies and lead to improved treatment outcome and fewer referrals.

11. Economic aspects

Estimated costs for GPM and usual care

This section estimates costs of treating patients with BPD (60.9% of all patients treated for personality disorders in VGR in 2022 or 2,400 patients) with GPM and usual care (UC). Different scenarios of treatment process and training requirement for both GPM and UC, as well as time allocation of the involved medical staff, were identified in discussion with the project group. The allocated time has then been transformed into costs using time allocation and wage rate (including employer's fee). The effect of the training was assumed to last for two years and a discounting rate of 3% was used for calculating the annual equivalent costs of training (Drummond et al., 2015). Training costs per patient were based on the assumption that all patients with BPD (2,400 in 2022) receive treatment.

GPM

In Table 2, costs of a one-year GPM intervention as delivered in McMMain et al. (2009), with weekly individual psychotherapy sessions are presented. Estimated total cost is approximately 41,000 SEK, with treatment provided by a physician/psychiatrist.

Table 2. Estimated costs (in SEK) per patient for individual treatment of GPM for a one-year period, based on time allocation from McMMain et al. (2009) and personnel costs from Statistics Sweden.

Scenario	Staff category	Time allocation (hours)	Cost per patient/session	Number of sessions	Total cost per patient
Yearlong individual treatment of GPM provided as in the McMMain et al (2009) study, delivered by physician (n=90)					
Scenario 1 (McMMain et al, 2009)	Treatment by physician (specialist in psychiatry)	1.0	672	52	34,944
	Group supervision of treating therapists (n=12*)	1.5	112	52	5,824
	GPM training	8.0		1	157
	Total				40,925

*) Eight psychiatrists, four psychologists/nurses

In Table 3 we present lower-cost scenarios with individual treatment provided by other staff categories than physicians, with fewer treatment sessions (as delivered in the study by Kramer et al., 2014), fewer supervision sessions, and a treatment model with only six group sessions provided by a team. However, for these scenarios there are no data in the literature regarding the treatment effects compared with usual care.

Estimated total costs per patient for treatment models with individual sessions range between approximately 5,000 SEK and 22,000 SEK, depending on staff category involved. With a group treatment model, two staff members dedicate 90 minutes each, and both go through a one-day training (8 hours) in GPM. On average, 10 patients participate in each group session. With this model, total cost per patient, including staff training, would be less than 1,000 SEK.

Table 3. Estimated costs (in SEK) per patient for different scenarios of individual treatment of GPM, based on time allocation from McMain et al. (2009) and Kramer et al (2014), respectively, but with half the amount of supervision, and for group treatment based on time allocation from Region Västra Götaland. Personnel costs are retrieved from Statistics Sweden.

Scenario	Staff category	Time allocation (h)	Cost per patient/session	Number of sessions	Total cost per patient
Yearlong individual treatment of GPM provided as in the McMain et al (2009) study, but delivered by other staff categories (n=90)					
Scenario 2 (VGR)	Treatment by nurse (psychiatry)	1.0	341	52	17,732
	Group supervision of treating therapists	1.5	112	26	2,912
	GPM training	8.0		1	157
	Total				20,801
Scenario 3 (VGR)	Treatment by psychotherapist	1.0	362	52	18,824
	Group supervision of treating therapists	1.5	112	26	2,912
	GPM training	8.0		1	157
	Total				21,893
10-week individual treatment of GPM provided as in the Kramer et al (2014) study, delivered by physician (n=38)					
Scenario 4 (Kramer et al. (2011))	Treatment by physician (specialist in psychiatry)	1.0	672	10	6,720
	Supervision of treating therapist	1.0	1,013	2	2,026
	GPM training	8.0		1	37
	Total				8,783
10-week individual treatment of GPM provided as in the Kramer et al (2014) study, but delivered by other staff categories (n=38)					
Scenario 5 (VGR)	Treatment by nurse (psychiatry)	1.0	341	10	3,410
	Supervision of treating therapist	1.0	682	2	1,364
	GPM training	8.0		1	19
	Total				4,793
Scenario 6 (VGR)	Treatment by psychotherapist	1.0	362	10	3,620
	Supervision of treating therapist	1.0	703	2	1,406
	GPM training	8.0		1	20
	Total				5,046
6-week group treatment provided by two team members					
Scenario 7 (VGR)	Treatment by 1 physician (specialist in psychiatry) & 1 nurse (psychiatry)	1.5	152	6	912
	GPM training	8.0		1	2
	Total				914

VGR, Region Västra Götaland

The different treatment models and scenarios vary in terms of number of sessions and categories of medical staff involved, and whether they are individual- or group-based. Given the heterogeneity of the patient population, there is no reason to expect that the brief, group-based version of GPM will be enough care for most patients. Since there are no data available to make a useful estimation of the number of patients that are suitable for treatment with GPM, or which of the models that are suitable for which patients, the cost analysis is limited to estimating the costs per patient only.

It could be expected that a majority of patients will need further treatment. Nevertheless, all patients with BPD are in need of the kind of structured psychoeducation offered with GPM after receiving their diagnosis. Even for patients needing further care, psychoeducation in itself can be assumed to have meaningful effects and augment further care, and also assures that the patients' right to receive accurate and relevant information regarding their condition is met.

Usual care

Costs for treating patients with BPD within UC using both individual and group sessions are presented in Table 4. Usual care typically involves both weekly individual sessions conducted by a physician and group sessions by a team of medical staff, as well as a psychologist providing telephone counselling. The group composition in UC with a higher number of medical staff, the combination of individual and group sessions, and the higher frequency of sessions (once per week for a whole year) drive the costs high. This combined intervention costs approximately 50,000 SEK per patient.

Table 4. Estimated costs (in SEK) for a combination of weekly individual and group sessions in usual care (DBT) for a one-year period, based on time allocation from McMMain et al., 2009 and as currently done in Region Västra Götaland, respectively, and personnel costs from Statistics Sweden

Service/cost component	Staff category	Time allocation (hours)	Cost per patient/session	Number of sessions in a year	Total cost per patient
Yearlong individual and group treatment of DBT as provided in the McMMain et al (2009) study, delivered by a combination of staff categories (n=90)					
Individual session	1 master-level clinician*	1.0	430	52	22,360
Group session (Skills group) (10 patients/group)	1 nurse (psychiatry), 1 psychotherapist, 1 psychiatrist, 4 assistant nurses, 1 social worker	2.0	458	52	23,816
Telephone coaching	Psychologist	2.0	688	52	398
Consultation team for therapists	1 physician (specialist in psychiatry), 1 nurse (psychiatry), 1 psychotherapist, 1 psychiatrist, 4 assistant nurses, 1 social worker	2.0	592	52	3,422
Training	Master-level clinician	40		1	50
Total					50,046

Yearlong individual and group treatment of DBT provided as currently done in VGR, delivered by physician and a combination of staff categories, respectively (n=2400)					
Individual session	1 physician (specialist in psychiatry)	0.8	504	52	26,208
Group session (10 patients/group)	1 physician (specialist in psychiatry), 1 nurse (psychiatry), 1 psychotherapist, 1 psychiatrist, 4 assistant nurses, 1 social worker	1.4	420	52	21,840
	1 physician (specialist in psychiatry), 1 nurse (psychiatry), 1 psychotherapist, 1 psychiatrist, 4 assistant nurses, 1 social worker	2.0	128	52	6,656
Consultation team for therapists	1 physician (specialist in psychiatry), 1 nurse (psychiatry), 1 psychotherapist, 1 psychiatrist, 4 assistant nurses, 1 social worker				
24-h crisis telephone counselling	Psychologist (total 3000 SEK)				1
Training	1 physician (specialist in psychiatry) & 1 nurse (psychiatry)	40	20	1	20
Total					5 4,725

*) McMain study: three psychiatrists, four psychologists, five unspecified clinicians, one nurse

Treatment costs for one year's treatment with GPM as provided in the study by McMain et al. (2009) are thus estimated at 41,000 SEK/patient (Table 2), compared with 50,000 SEK/patient for usual care (DBT; Table 4).

In the different VGR scenarios (Table 3), costs for patients where group-based, six-session GPM treatment is sufficient, would be less than 1,000 SEK/patient. If GPM group treatment is supplemented with 10-session individual treatment, the total cost would range between 6,000-10,000 SEK/ patient (Table 3). If GPM group treatment needs to be supplemented with individual, weekly sessions for a year, total costs would be 22,000-42,000 SEK/patient, depending on staff category providing the treatment (Table 3). Choice of treatment model is primarily influenced by the severity of the disease. These amounts can be compared with the total cost per patient for UC treatment estimated at 50,000-55,000 SEK (Table 4).

The cost analysis is a partial economic analysis and does not consider treatment effects. The treatments' health effects need to be estimated for a complete economic analysis which would provide more complete cost-benefit information. Nevertheless, these estimated costs, comparing GPM and UC, may be useful for understanding the financial burden to VGR while considering the feasibility of implementing GPM.

12. Ethical aspects

Research on the effectiveness of GPM for the treatment of individuals with BPD is in early development. The first clinical evaluation trial (McMain et al., 2009; 2014), included in this HTA, did not reveal significant differences compared with the more established psychological method DBT, regarding several relevant outcomes. However, more data from controlled trials are needed before reliable conclusions can be drawn about treatment effects and possible adverse effects of GPM.

A diagnosis of BPD is conferred if an individual demonstrates five of nine possible diagnostic criteria, making BPD presentation very heterogeneous. Severity of the disorder ranges from mild (non-impairing) to severe to the extent that people may receive mandatory inpatient treatment due to suicidal behaviour. There is currently no evidence to indicate that GPM produces different outcomes than other treatments for BPD such as DBT and MBT with respect to disease severity.

Considering the diverse presentations in patients with BPD, it's highly unlikely that a single treatment will suffice for the entire patient population. Given its common prevalence and the complexities associated, it might also be seen as unethical to not introduce GPM alongside the existing evidence-based treatments. This could be a means of both increasing access to care and better catering to a diverse patient population. There is currently no evidence regarding GPM in relation to the health of third parties (such as family or other loved ones).

At the time of conducting this HTA, there were no indications of any benefits of GPM compared with other treatment options analysed in this HTA-report and there are no published data regarding risks of GPM, precluding a benefit/risk assessment. The absence of data regarding risk is not a limitation particular to GPM; rather, it is a limitation of the field of evidence-based treatments for personality disorders. Although treatment drop-out is accepted as inevitable in psychiatry research, it would advance the field to track and analyse the reasons participants give for discontinuing treatments and research by extension.

Implementation of GPM would not contradict the Human Dignity principle or the Swedish Discrimination Act, as the method could be offered to all patients diagnosed with BPD. However, not all patients are likely to be suitable or receptive to this treatment method, and all patients with different needs cannot be treated with the same method. Particularly those with more severe symptoms will likely require more intensive treatment than GPM. The GPM method is designed to be adaptable to the patient's needs and circumstances. However, a possible introduction of GPM in routine care could lead to displacement effects of more comprehensive treatments, such as DBT.

As GPM is a non-specialised treatment for personality disorder it can be implemented effectively in settings with limited resources, as demonstrated by Ridolfi et al. (2020). This is a promising contrast from other specialised evidence-based treatments that are multi-component, can only be delivered by those with advanced training, and are accordingly comparatively more expensive. Depending on chosen treatment model (group or individual treatment, length of treatment), GPM could yield substantial cost savings compared to conventional treatment, e.g. DBT, which could potentially free up resources for other patient groups.

13. Discussion

Summary of main results

Based mainly on one RCT (McMain et al., 2009, 2014) that compared the method at issue, GPM, with another psychotherapeutic treatment, DBT, this HTA showed that, for most assessed outcomes, there were no differences in effects between the two methods. Certainty of evidence was assessed as low due to serious study limitations and serious to very serious imprecision. For most outcomes, however, there were significant improvements with both GPM and DBT from baseline to end of treatment, which were maintained throughout the 2-year follow-up period. Based on one non-RCT (Ridolfi et al., 2020) that compared GPM with no intervention, there was a significant effect on symptom remission, also with low certainty of evidence.

Overall completeness and applicability of evidence

The PICO in this HTA was defined in as inclusive terms as possible to include all relevant publications in the field. Despite this, only four studies met our PICO and could be included. For most outcomes, certainty of evidence was assessed for the comparison GPM versus DBT. These are two active treatment including similar psychotherapy approaches, but in the RCT by McMain et al. (2009) performed at different intensities (treatment lengths). It could be expected that there would only be a small or no difference between the two interventions. The degree of BPD severity was not specified in the study, whereas clinical experience indicates that patients with more severe symptoms require a more intensive treatment strategy. This may limit the applicability of our findings to the whole BPD population. For one of the outcomes, symptom remission, certainty of evidence was also assessed for the comparison of GPM vs no treatment (wait list) based on the non-RCT by Ridolfi et al. (2020). The magnitude of symptom reduction was large, thus, the certainty of evidence was upgraded one step.

We therefore concluded low certainty of evidence for little or no difference between GPM and DBT, and low certainty of evidence for greater symptom remission with GPM than with no treatment.

Agreements and disagreements with other studies and reviews

Initially, it should be emphasised that the current state of research regarding the treatment of BPD and self-harm remains wanting (cf. Storebø et al., 2020, Stoffers-Winterling et al., 2022). Relating this study to other reviews becomes complex since GPM has primarily been used as a control group (referred to as "treatment as usual"). In meta-analyses, GPM has thus been grouped with a variety of interventions of differing intensities and qualities.

The most comprehensive meta-analysis to date (Storebø et al., 2020) provides some support for the most studied forms of specialised therapies (such as DBT and MBT) being more effective than treatment as usual or waitlists for several outcomes, including self-harm. However, this conclusion is based on studies where DBT and MBT are compared to treatment as usual of varying quality. When controlling for the design of treatment as usual, specialised treatments seem to have less of an advantage over manualised treatment as usual, such as GPM, than they do over other forms of treatment as usual (Cristea et al., 2017).

The study by Ridolfi et al. (2020) is not included in these meta-analyses. The findings from that study seem to resonate with other research, suggesting that, psychoeducation as a standalone modality can be efficacious for patients with BPD (Zanarini and Frankenburg, 2008, Zanarini et al.,

2018). However, in the context of the studies by Zanarini and colleagues, the most consistent evidence for the efficacy of psychoeducation concerns its impact on facets of BPD-related challenges (i.e. impulsivity) (Stoffers-Winterling et al., 2022).

Implications for research

With GPM being a fairly recently developed treatment method, research is only emerging. Hence, there is a need for more studies of adequate power and design that investigate effects on relevant outcomes before any firm conclusions can be drawn regarding the method's benefits and risks. Both patients' and staff's experiences of using the method also need to be explored.

14. Future perspectives

Scientific knowledge gaps

Our literature search did not identify any studies on GPM for other personality disorders than BPD nor any studies on self-harm behaviours that were not related to BPD. With only one RCT that compared GPM with other psychiatric treatment, there is a need for further well-designed, randomised, trials, with long-term follow-up. Comorbidity with other psychiatric conditions was only investigated in one study. Another knowledge gap identified in this HTA is a lack of studies that describe the patients' experiences of being treated with GPM, as well as the important perspective of family and other loved ones.

Ongoing research

The search for ongoing studies on GPM identified three records. Two of those have been completed and published and are included in this HTA. One record (NCT03717818) was for an RCT by Kramer et al., comparing a brief GPM intervention (ten sessions over four months with the final follow-up at 12 months after inclusion) with treatment as usual. The trial planned to recruit 80 participants, with Zanarini Borderline Personality Disorder Scale as the primary outcome, and to be completed by December 2022. No publication had been identified at the time of this HTA's completion.

15. Participants in the project

The question was nominated by

Aase Eriksson, Head of National team for self-harming, Region Västra Götaland, NU-sjukvården, Vänersborg, Sweden

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Declaration of interests

None of the authors have any conflicts of interest to declare.

Project time

The HTA was performed during the period of 30 Nov 2022 – 24 Nov 2023.

Literature searches were made on 10 January 2023.

Appendix 1: PICO, study selection, search strategies, and references

Question(s) at issue: In patients with personality disorder and/or self-harm behaviour, what are the benefits and risks of treatment with General/Good Psychiatric Management as a stand-alone or adjunct treatment, compared with any other intervention or no intervention in terms of mortality, suicide/attempted suicide, self-harm, symptom remission, complications, health care utilisation, disability/function and patient experience?

PICO: (*P=Patient I=Intervention C=Comparison O=Outcome*)

P	Patients with personality disorder and/or self-harm behaviour
I	General Psychiatric Management/Good Psychiatric Management as a stand-alone or adjunct treatment
C	Any other intervention or no intervention
O	<u>Critical for decision-making</u> Mortality Suicide/attempted suicide Self-harm Symptom remission Health-related quality of life <u>Important for decision-making</u> Healthcare utilisation Disability/function Patient experience Complications

Eligibility criteria

Study design:

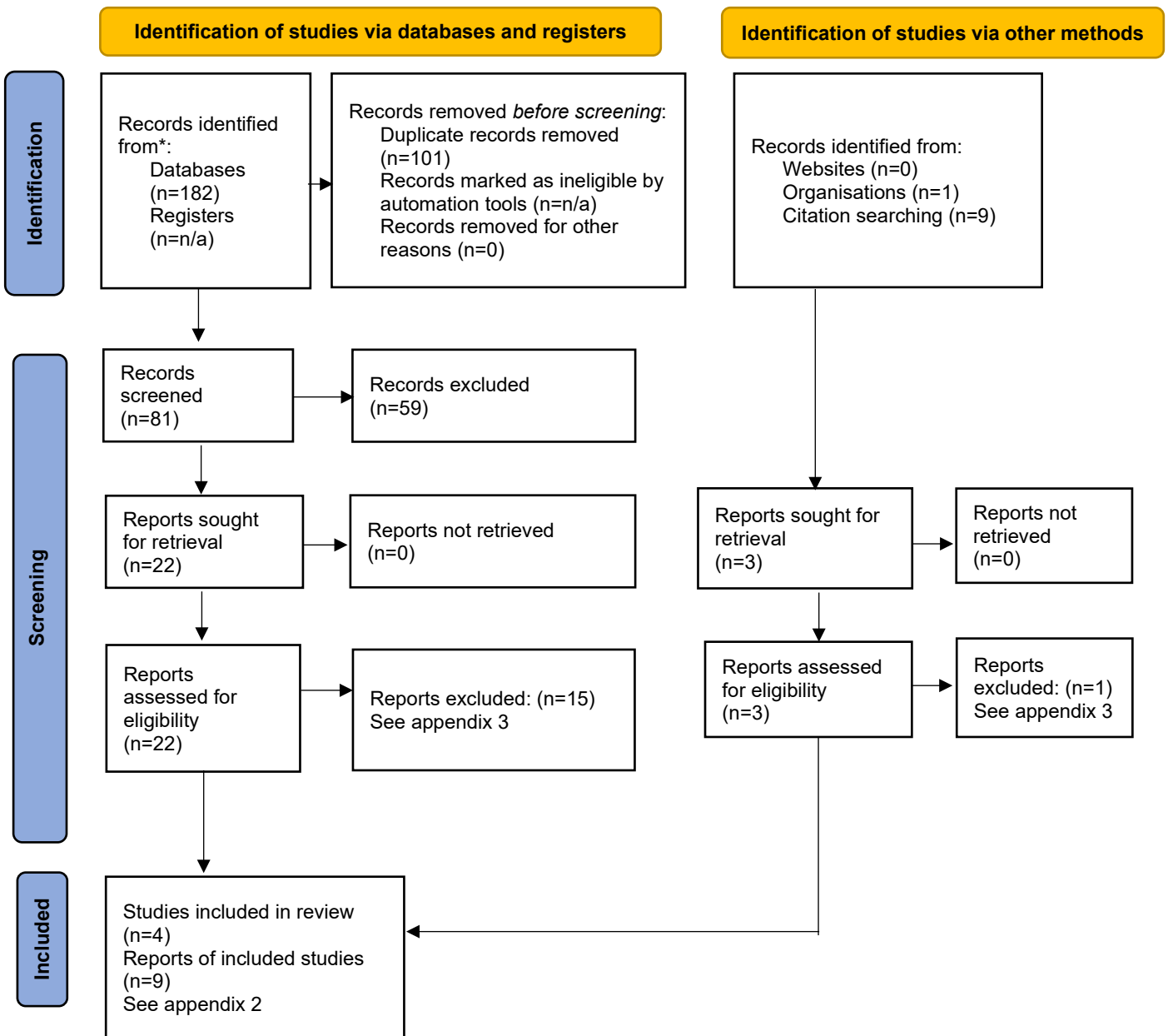
Systematic reviews
Randomised controlled trials (RCTs)
Non-randomised controlled studies (non-RCTs)
Case series if ≥ 5 patients
Qualitative studies

Language:

English, Swedish, Danish, Norwegian

Selection process – flow diagram

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources



From: Page MJ et al, 2021

Database: Medline MEDLINE(R) ALL (Ovid)

Date: 10 Jan 2023

No. of results: 44

#	Searches	Results
1	((General or good) adj psych* adj management*).ab,kf,ti.	44

Database: Embase 1974 to 2023 January 09 (Ovid)

Date: 10 Jan 2023

No. of results: 53

#	Searches	Results
1	((General or good) adj psych* adj management*).ab,kf,ti.	53

Database: The Cochrane Library

Date: 10 Jan 2023

No. of results: 22

Clinical trials 22

ID	Search	Hits
#1	((General or good) NEXT psych* NEXT management*);ti,ab,kw (Word variations have been searched)	22

Database: PsycINFO (EBSCOhost)

Date: 10 Jan 2023

No. of results: 63

#	Query	Results
S1	AB (((General or good) W0 psych* W0 management*) OR TI (((General or good) W0 psych* W0 management*))	63

The web-sites of **Statens beredning för medicinsk och social utvärdering (SBU)** and **Folkhelseinstituttet** were visited 10 Jan 2023. Nothing relevant to the question at issue was found. Search terms used: good psychiatric management, general psychiatric management, GPM

Reference lists

A comprehensive review of reference lists brought 9 new records.

Reference lists

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Project: General psychiatric management

Appendix 2 – Characteristics of included studies

Author Year Country	Study design	Length of treatment	Length of follow-up	Study groups; Intervention vs control	Patients (n)	Mean age (SD) (years)	Men (%)	Outcome variables
McMain 2009 Canada	RCT	12 months	12 months	GPM vs DBT	180	30.4 (9.9)	13.9	Mortality Suicide attempts Self-harm Symptom remission: psychiatric symptoms, anger, depression, inter-personal functioning Health-related quality of life Healthcare utilisation
McMain 2012 Canada	RCT (same trial as above)	12 months	36 months (since start of treatment)	GPM vs DBT	ITT: 180 PP: 167	30.4 (9.9)	13.9	Mortality Suicide attempts Self-harm Symptom remission: symptom distress, anger depression Interpersonal functioning Health-related quality of life Healthcare utilisation
Boritz 2016 Canada	RCT (same trial as above)	12 months	36 months	GPM vs DBT Outcomes BPD v. BPD + PTSD	180	30.4 (9.9)	13.9	Mortality Symptom remission: symptom severity, symptom distress
Kramer 2011 Switzerland	RCT (treated as case series)	10 weeks	3 months	GPM (I1) vs GPM+MOTR (I2)	25 I1: 14 I2: 11	I1: 31.3 (8.2) I2: 30.3 (12.4)	I1: 18 I2: 43	Symptom remission: symptom distress, (OQ-45 total score, BSL-23 total score) Disability/function: interpersonal functioning (Inventory of Interpersonal Problems–64, total score (IIP total)).
Kramer 2014 Switzerland	RCT (treated as case series)	10 weeks	3 months	GPM (I1) vs GPM+MOTR (I2)	85 I1: 43 I2: 42	I1: 31 (11) I2: 35 (10)	I1: 21 I2: 42	Symptom remission: interpersonal relationships, social role (OQ-45 total score, BSL-23 total score), Borderline symptomatology (Borderline Symptom List; BSL-23) Disability/function: interpersonal functioning (Inventory of Interpersonal Problems; IIP total score)

Project: General psychiatric management

Appendix 2 – Characteristics of included studies

Author Year Country	Study design	Length of treatment	Length of follow-up	Study groups; Intervention vs control	Patients (n)	Mean age (SD) (years)	Men (%)	Outcome variables
Berthoud 2017 Switzerland	RCT (same as above)	10 weeks	10 weeks	GPM (I1) vs GPM+MOTR (I2)	50 I1: 25 I2: 25	31.6 I1: 31 (10) I2: 32 (9)	I1: 12 I2: 32	Symptom remission: symptom distress, interpersonal relationships, social role (OQ-4: total score, BSL-23 total score)
Maillard 2017 Switzerland	Case series (subsample from Kramer 2014)	10 weeks	10 weeks	GPM	10	33 (4)	10	Symptom remission Outcome Questionnaire – 45.2; OQ-45 (total score) Metacognition Assessment Scale-Revised (MAS-R) MAS-R total scale score Understanding of one’s own mind (UM subscale) Understanding of other’s mind (UOM subscale) Mastery (M subscale)
Maillard 2020 Switzerland	Case series (subsample from Kramer 2014)	10 weeks	10 weeks	GPM (I1) + GPM+MOTR (I2)	37 GPM: 17 GPM+MOTR: 20	33.8 GPM: 33.7 (1.2) GPM+MOTR: 33.8 (1.4)	30 I1: 18 I2: 40	Symptom remission Outcome Questionnaire – 45.2; OQ-45 Total Score) Metacognition Assessment Scale-Revised (MAS-R) MAS-R total scale score Understanding of one’s own mind (UM subscale) Understanding of other’s mind (UOM subscale) Mastery (M subscale)

Project: General psychiatric management

Appendix 2 – Characteristics of included studies

Author Year Country	Study design	Length of treatment	Length of follow-up	Study groups; Intervention vs control	Patients (n)	Mean age (SD) (years)	Men (%)	Outcome variables
								Plus all subfunction scores comprising each subscale, for the entire sample: Monitoring within the UO subscale, Differentiation, Integration, Monitoring within the UM subscale, Decentration, Basic requirements, First-level strategies, Second-level strategies, Third-level strategies
Ridolfi 2020 Italy	Non-randomised controlled trial	6 weeks	8 weeks	GPM vs non-invasive TAU/wait list	96	GPM: 35 (10) TAU: 34 (10)	GPM: 52 TAU: 33	Symptom remission assessed with the Zanarini Rating Scale for DSM-IV Borderline Personality Disorder (ZAN-BPD): Total score; Affect sector; Cognitive sector; Impulsivity Sector; Interpersonal sector

DBT: Dialectical behavioural therapy; GPM: General psychiatric management; ITT: Intention to treat; MOTR: Motive-oriented therapeutic relationship method; PP: Per protocol; TAU: Treatment as usual

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.1

Outcome variable: Mortality

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention	Control				
McMain Canada 2009	RCT – single blind trial	180	Dropped out prior to randomisation: 25 Dropped out in FU phase: DBT: n=35 (38.9%) GPM: n=34 (37.8%)	<u>GPM</u> Mortality: 0	<u>DBT</u> Mortality: 0		+	?	-
McMain Canada 2012	RCT – single blind trial (2-year follow-up of above trial)	180	Dropouts at 36 months: 70/180 (39%)	<u>GPM</u> Mortality: 0	<u>DBT</u> Mortality: 2 (deaths from natural causes)	In addition to study follow-ups, the Ontario death registry was searched.	+	?	-

GPM: General psychiatric management; DBT: Dialectic behavioural therapy

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.2

Outcome variable: Suicide/attempted suicide

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD)	Control Mean (SD)				
McMain 2009 Canada McMain 2012 Canada	RCT – single blind trial 2-year follow-up	180	Dropped out prior to randomisation: n=25 Dropped out in FU phase: GPM: n=34 (37.8%) DBT: n=35 (38.9%)	<u>GPM</u> <u>Number of suicidal episodes</u> Baseline: 1.86 (6.31) (37.5%) 12 months: 0.32 (2.09) (6.6%) within-group p=0.01 Between-group, ns 24 months: 0.09 (0.33) (7.4%) p-value NR 36 months: 0.29 (1.15) (12.1%), ns Time effect for FU phase: RR 1.26 (95% CI 0.48-3.28), z 0.47, ns Group effect for FU phase: RR 0.87 (95% CI 0.23-3.21), z -0.21, ns	<u>DBT</u> <u>Number of suicidal episodes</u> Baseline: 1.30 (3.60) (39.3%) 12 months: 0.33 (1.31) (10.1%) within-group p=0.01 24 months: 0.07 (0.26) (6.9 %) p-value NR 36 months: 0.55 (2.42) (8.2%) p = ns	Treatment duration was 1 year Frequency and severity of suicidal episodes were assessed every 4 months. Data collected with the validated instrument The Suicide Attempt Self- Injury Interview (SASII), a structured interview that assesses self-injury variables. Interviewers categorise each incident as either a nonsuicidal self- injury, an ambivalent suicide attempt, a nonambivalent suicide attempt, or a failed suicide. SASII comprises six standard scales, with 2 to 8 items each, and 13 individual items. Number of self-harm episodes is an open numerical item in the beginning of the instrument. Severity of self- harm episodes was operationalised as maximum medical risk of suicide and self-harm episodes, measured using lethality of method and treatment received for each suicidal and self- harm episode on a six-point scale from 1 Very low to 6 Severe. Maximum score is the highest score across episodes within the assessment period. Time and group effect coefficients based on generalised-estimating equation analyses from baseline to 12 months.	+	?	?

Project: General Psychiatric Management

* + No or minor problems ? Some problems - Major problems

Appendix 4.2

Outcome variable: Suicide/attempted suicide

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD)	Control Mean (SD)				
Boritz 2016 Canada	Secondary analysis of McMain 2009 and McMain 2012	180	Dropped out prior to randomisation: n=25 Dropped out in FU phase: GPM: n=34 DBT: n=35	No additional impact of comorbid PTSD on frequency of suicide attempts at end of treatment or follow-up Absolute data NR		This secondary analysis of McMain 2009 explored the influence of PTSD on treatment outcomes.			

DBT: Dialectic Behavioural Therapy; FU: Follow-up; GPM: General Psychiatric Management; ns: not significant; NR: Not reported; PTSD: Posttraumatic stress disorder

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.3

Outcome variable: Self-harm

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
McMain 2009 Canada	RCT – single blind trial	180	Dropped out prior to randomisation: n=25 Dropped out in FU phase: GPM: n=34 (37.8%) DBT: n=35 (38.9%)	<u>GPM</u> <u>Frequency of self-harm episodes</u> Baseline: 32.19 (81.94) 12 months: 12.87 (51.45) Time effect: OR 0.4, p<0.001 Group effect: OR 0.92, ns <u>Severity of self-harm episodes</u> Baseline: 3.67 (2.64) 12 months: 1.32 (2.03) Time effect: -0.20, p<0.0001 Group effect: -0.02, ns <i>Both groups made clinically significant clinical improvements (effect x time) that were not different between GPM and DBT on both measures</i>	<u>DBT</u> <u>Frequency of self-harm episodes</u> Baseline: 20.94 (33.28) 12 months: 4.29 (9.32) <u>Severity of self-harm episodes</u> Baseline: 4.26 (2.87) 12 months: 1.69 (2.37)	Treatment duration was 1 year. Frequency and severity of self-harm episodes were assessed every 4 months. Data collected with the validated instrument The Suicide Attempt Self-Injury Interview (SASII), described in Appendix 4.2. Time and group effect coefficients based on generalised-estimating equation analyses from baseline to 12 months. 95% confidence intervals for OR not reported.	+	?	?

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.3

Outcome variable: Self-harm

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
McMain 2012 Canada	RCT (Follow up of McMain, 2009)	180	Dropouts at 36 months: 70/180 (38.9%)	<u>GPM</u> <u>Number of nonsuicidal self-injury behaviours</u> Baseline: 20.41 (39.98) (87.5%) 24 months: 2.06 (8.01) (33.8%) 36 months: 1.09 (4.31) (31.0%) Time effect: RR 0.56 (95% CI 0.30-1.05), ns Group effect: RR 1.17 (95% CI 0.35-3.87), ns <u>Severity of nonsuicidal self-injury behaviours</u> unchanged from end of treatment at 12 months to last follow-up at 36 months (no absolute data reported) No significant differences between groups.	<u>DBT</u> <u>Number of nonsuicidal self-injury behaviours</u> Baseline: 21.65 (35.20) (84.3%) 24 months: 2.48 (7.34) (29.3%) 36 months: 2.18 (7.77) (24.5%) <u>Severity of nonsuicidal self-injury behaviours</u> unchanged from end of treatment at 12 months to last follow-up at 36 months (no absolute data reported)	Time and group effect coefficients based on mixed-effects linear regression analyses and representing estimates of differences in slope.	+	?	?
Boritz 2016 Canada	RCT (Follow up/ secondary)	180	Dropped out prior to	<u>GPM</u>	<u>DBT</u>	This secondary analysis explored the impact of PTSD comorbidity.	+	?	?

Project: General Psychiatric Management

* + No or minor problems ? Some problems - Major problems

Appendix 4.3

Outcome variable: Self-harm

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
	analysis of McMain 2009 and McMain 2012)		randomisation: n=25 Dropped out in FU phase: GPM: n=34 DBT: n=35	No additional impact of comorbid PTSD on frequency of non-suicidal self-harm at end of treatment or follow-up Absolute data NR					

CI: Confidence interval; DBT: Dialectic Behavioural Therapy; GPM: General Psychiatric Management; NR: Not reported; OR: Odds ratio; RR: Relative rate

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
McMain Canada 2009	RCT – single blind trial	180	Dropped out prior to randomisation: n=25 Dropped out in FU phase: GPM: n=34 DBT: n=35	<u>GPM</u> <u>BPD symptom severity (ZAN-BPD total score)</u> Baseline: 14.94 (6.59) 12 months: 8.16 (5.79) Time effect, p=<0.001 Group effect, ns <u>Depression (BDI)</u> Baseline: 35.40 (10.6) 12 months: 24.83 (14.83) Time effect, p= <0.001 Group effect, ns <u>Anger (STAXI anger expression out subscore)</u> Baseline: 17.60 (5.51) 12 months: 15.96 (5.11) Time effect, p=0.004 Group effect, ns <u>Symptom distress (SCL-90, total score)</u> Baseline: 1.85 (0.76) Discharge: 1.36 (0.82) Time effect, p= 0.001	<u>DBT</u> <u>BPD symptom severity (ZAN-BPD total score)</u> Baseline: 15.49 (6.14) 12 months: 7.93 (6.11) <u>Depression (BDI)</u> Baseline: 37.19 (12.46) 12 months: 22.18 (16.14) <u>Anger (STAXI anger expression out subscore)</u> Baseline: 17.92 (5.29) 12 months: 15.81 (5.19) <u>Symptom distress (SCL-90, total score)</u> Baseline: 1.91 (0.77) Discharge 1.35 (0.89)	Zanarini Rating Scale for Borderline Personality Disorder (scale 0 to 36, higher score indicates more severe symptoms)	+	?	?

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
				Group effect, ns					
McMain Canada 2012			Dropped out prior to randomisation: n=25 Dropped out in FU phase: GPM: n=34 DBT: n=35	<u>GPM</u> <u>BPD symptom severity (ZAN-BPD total score)</u> Baseline: 14.94 (6.59) 24 months: 8.09 (5.89) 36 months: 6.66 (5.49) Time effect FU phase, ns Group effect FU phase: ns <u>Depression (BDI)</u> Baseline: 35.40 (10.6) 24 months: 21.67 (14.82) 36 months: 18.05 (13.77) Time effect FU phase: p=0.0002 Group effect FU phase: p=0.004 <u>Anger (STAXI anger expression out subscore)</u> Baseline: 17.6 (5.51) 24 months: 15.79 (5.12) 36 months: 14.40 (3.47) Time effect FU phase, p= 0.0006 Group effect FU phase, ns	<u>DBT</u> <u>BPD symptom severity (ZAN-BPD total score)</u> Baseline: 15.49 (6.14) 24 months: 8.17 (6.10) 36 months: 8.29 (6.35) <u>Depression (BDI)</u> Baseline: 37.15 (12.46) 24 months: 22.24 (16.40) 36 months: 24.45 (18.65) <u>Anger (STAXI anger expression out subscore)</u> Baseline: 17.92 (5.19) 24 months: 14.48 (4.41) 36 months: 15.95 (4.80)		+	?	?

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
				<u>Symptom distress (SCL-90, total score)</u> Baseline: 1.85 (0.76) 24 months: 1.20 (0.85) 36 months: 1.03 (0.8) Time effect FU phase, p= 0.006 Group effect FU phase, ns	<u>Symptom distress (SCL-90, total score)</u> Baseline: 1.91 (0.77) 24 months: 1.20 (0.85) 36 months: 1.26 (0.95)				
Boritz Canada 2016	Secondary analysis of McMain 2009 and McMain 2012	180	Dropped out prior to randomisation: n=25 Dropped out in FU phase: GPM: n=34 DBT: n=35	<u>GPM</u> For patients with BPD only, greater improvement in BPD symptoms in DBT than GPM: Z= 2.25, p= 0.024 (95% CI 0.024 to 0.356). (Effect size not reported by treatment group)		Rate of PTSD: DBT 35.5%, GPM 43.3%. Significantly higher levels of global psychological distress measured with SCL-90 in patients with vs without comorbid PTSD (Z=3.22, p=0.001, 95% CI 0.139 to 0.572) at end of treatment in both treatment groups. No significant difference at two-year follow-up. No difference between treatment groups. No significant difference in BPD symptoms measured with Zan-BPD between BPD+ PTSD and BPD only.			
Maillard Switzerland	Case series	10	-	<u>GPM</u>		Metacognition, assessed with the Metacognition Assessment Scale-Revised (MAS-R).	+	?	-

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
2017				<u>Metacognition (MAS-R total score)</u> Baseline: 1.77 (0.36) 10 th session: 1.93 (0.48) ns <u>Understanding of one's own mind (UM subscale)</u> Baseline: 2.24 (0.16) 10 th session: 2.37 (0.18) ns <u>Understanding of other's mind (UOM subscale)</u> Baseline: 1.49 (0.13) 10 th session: 1.56 (0.14) ns <u>Mastery (M subscale)</u> Baseline: 1.58 (0.11) 10 th session: 1.88 (0.17) ns <u>OQ-45 (total score)</u> Baseline: 71-144 10 th session: 19-130 <i>M and SD not reported</i>		Questions are rated 1-5 from "scarce" to "sophisticated" and averaged for a total score. Higher score is better.			
Maillard Switzerland	Case series	37	-	<u>GPM</u> <u>OQ-45 Total Score</u>		All scores are pooled for all participants, not by GPM and GPM+MOTR.	+	?	?/-

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
2020				Baseline: 93.8 (28) Discharge: 84.8 (27) ns <u>GPM+GPM/MOTR</u> <u>OQ-45 Total Score</u> Baseline: 102.4 (24.8) Discharge: 81.7 (23.9) p< .001 <u>MAS-R total:</u> Baseline 1.65 (0.47) Discharge: 1.81 (0.52) ns <u>Understanding of one's own mind</u> Baseline: 1.81 (0.54) Discharge: 2 (0.60) ns <u>Monitoring</u> Baseline: 2.1 (0.67) Discharge: 2.25 (0.72) ns <u>Differentiation</u> Baseline: 1.32 (0.49) Discharge: 1.66 (0.60) ns		Metacognition, assessed with MAS-R. Total Scales, Subscales and subfunction scales are presented by the authors. Subfunction scales contribute to subscales. For example, <i>Monitoring, Differentiation and Integration</i> all comprise the Understanding of one's own Mind/UM subscale). OQ-45 total scores listed in text on p. 317			

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
				<u>Integration</u> Baseline: 1.41 (0.54) Discharge: 1.60 (0.54) ns <u>Understanding of other's mind</u> Baseline: 1.40 (0.43) Discharge: 1.65 (0.50) ns <u>Monitoring</u> Baseline: 1.42 (0.45) Discharge: 1.74 (0.60) ns <u>Decentration</u> Baseline: 1.33 (0.56) Discharge: 1.37 (0.45) ns <u>Mastery</u> Baseline: 1.59 (0.50) Discharge: 1.65 (0.50) ns <u>Basic requirements</u> Baseline: 1.82 (0.72) Discharge: 1.87 (0.62) ns					

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
				<u>First level strategies</u> Baseline: 1.54 (0.44) Discharge: 1.54 (0.50) ns <u>Second level strategies</u> Baseline: 1.57 (0.52) Discharge: 1.95 (0.69) ns <u>Third level strategies</u> Baseline: 1.59 (0.65) Discharge: 1.60 (0.60) ns					
Ridolfi Italy 2020 SIL	Non-randomised clinical trial	96 I:48 C: 48	none	<u>GPM</u> <u>ZAN BPD total</u> Baseline: 22 (7.6) 6 weeks: 12.3 (7.4) 8 week FU: 13.0 (7.8) Between-group difference: 5.6, p<0.001 effect p value <.001 for time effect p value <.001 for group	<u>Non-intensive TAU/control</u> <u>ZAN BPD total</u> Baseline: 23.5 (6.2) 6 weeks: 22.2 (7.1) 8 week FU: 20.1 (7.4) effect p value <.001 for time effect p value <.001 for group effect p value <.001 for time x group	Primary outcomes measured at baseline, at 6w & 8w FU (ZAN BPD overall / Total scores, ZAN BPD Affect sector, ZAN BPD Cognitive sector, ZAN BPD Impulsivity sector, ZAN BPD Interpersonal Sector	+	?	?

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
				effect p value <.001 for time x group <u>ZAN BPD Affect sector</u> Baseline: 8.7 (4.2) 6 weeks: 5.3 (4.6) 8-weeks FU: 5.45 (4.2) Between-group difference: 2.25, p <.001 effect p value <.001 for time effect p value <.001 for group effect p value <.001 for time x group <u>ZAN BPD Cognitive sector</u> Baseline: 5.2 (2.1) 6 weeks: 3 (2.1) 8-week FU: 3.3 (2.1) Between-group difference: 1.4, p <.001	<u>ZAN BPD Affect sector</u> Baseline: 8.5 (2.6) 6 weeks: 8.2 (3.0) 8-weeks FU: 7.5 (3.2) effect p value <.001 for time effect p value <.001 for group effect p value <.001 for time x group <u>ZAN BPD Cognitive sector</u> Baseline: 5.2 (1.8) End of tx: (6 weeks) 5.3 (1.8) 8-week FU: 4.7 (2.0)				

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
				effect p value <.001 for time effect effect p value <.001 for group effect effect p value <.001 for time x group <u>ZAN BPD Impulsivity sector</u> Baseline: 3.5 (2.2) 6 weeks: 2 (1.6) 8-week FU: 2.4 (1.8) Between-group difference: -0.2, p <.0.001 effect p value <.001 for time effect effect p value <.001 for group effect effect p value.100 for time x group <u>ZAN BPD Interpersonal sector</u> Baseline: 5.2 (2) 6 weeks: 3 (1.9) 8-week FU: 2.9 (2.1) effect p value <.001 for time	effect p value <.001 for time effect effect p value <.001 for group effect effect p value <.001 for time x group <u>ZAN BPD Impulsivity sector</u> Baseline: 4.4 (1.8) 6 weeks: 3.4 (2.0) 8-week FU: 3.1 (1.9) effect p value <.001 for time effect effect p value <.001 for group effect effect p value.100 for time x group <u>ZAN BPD Interpersonal sector</u> Baseline: 5.5 (1.2) 6 weeks: 5.3 (2.0) 8-week FU: 4.7 (2.0)				

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
				effect p value <.001 for group effect p value <.001 for time x group	effect p value <.001 for time effect p value <.001 for group effect p value <.001 for time x group				
Kramer Switzerland 2011	Pilot study of RCT treated as case series	25	GPM: n=8 GPM+MOTR: n=2	<u>GPM</u> OQ-45 tot “Residual gains based on actual means” -5.14 (SD 10.58) <u>GPM+MOTR</u> OQ-45 tot “Residual gains based on actual means” -11.91 (SD 15.76)		No overall effect, some variation at subscale level not included in the hypothesis.	+	?	-
Kramer Switzerland 2014	RCT treated as case series	85	Dropped out prior to randomisation: n=11 Dropped out in FU phase: n=14	<u>GPM</u> <u>OQ-45 total</u> Baseline: 94.50 (26.38) 10 weeks: 86.13 (25.41) p=NR <u>BSL-23</u> Baseline: 1.74 (0.92) 10 weeks: 1.51 (0.97) p=NR <u>GPM+MOTR</u>		p-values not separately reported for GPM and GPM+MOTR outcomes, but analyses of each subscale showed significant within-group differences for all outcomes (time effect, p<0.05). Main outcome: Outcome questionnaire 45.2 (OQ-45). Validated scale comprising 45 items from 1 (never) to 4 (always) assessing results of psychotherapy, includes a global score and three	+	+/?	+/?

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
				<u>OQ-45 total</u> Baseline: 98.14 (23.66) 10 weeks: 75.97 (25.37) p=NR <u>BSL-23</u> Baseline: 1.87 (0.96) 10 weeks: 1.58 (0.99) p=NR		subscale scores. Lower value better. Borderline Symptom List (BSL-23). Validated. scale comprising 23 items from 0 (absent) to 4 (clearly present). Lower value better.			
Berthoud Switzerland 2017	RCT treated as case series	50/37 (global distress)	None	<u>GPM</u> <u>OQ-45 total, mean frequencies (%) (SD)</u> Baseline: 102.92 (24.93) Penultimate: 91.13 (26.31) Δ -11.83 (21.19) p <0.01 <u>BSL-23, mean frequencies (%) (SD)</u> Baseline: 1.93 (0.88) 10 weeks: 1.78 (1.04) Δ -0.16 (0.97) p<0.01 <u>Global distress, mean frequencies (%)*</u> Baseline: 62.9 10 weeks: 46.5 p<0.01		p-values not separately reported for GPM and GPM+MOTR outcomes, but analyses of total score and each subscale showed significant within-group differences for all outcomes (time effect, p<0.05). *Absolute frequencies of global distress, measured with The Classification of Affective-Meaning States.SD not reported for global distress	-	?	-

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.4

Outcome variable: Symptom remission

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
				<p><u>GPM+MOTR</u></p> <p><u>OQ-45 total, mean frequencies (%)</u> (SD) Baseline: 103.36 (24.00) 10 weeks: 77.25 (25.23) Δ -28.65 (27.11); p<0.01</p> <p><u>BSL-23, mean frequencies (%)</u> (SD) Baseline: 2.16 (0.82) 10 weeks: 1.71 (0.87) Δ -0.35 (0.76); p<0.01</p> <p><u>Global distress, mean frequencies (%)</u> (%)* Baseline: 65.4 10 weeks: 40.6 p<0.01</p>					

DBT: Dialectic Behaviour Therapy; FU: Follow-up; GPM: General Psychiatric Management; MOTR: Motive-oriented therapeutic relationship; RCT: Randomised controlled trial

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.5

Outcome variable: Health-related quality of life

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention	Control				
McMain 2009 Canada	RCT – single blind trial	180	Dropped out prior to randomisation: 25 Dropped out in FU phase: DBT: n=35 (38.9%) GPM: n=34 (37.8%)	<u>GPM</u> EQ-5D Baseline: 55.29 (SD 19.41) 12 months: 59.41 (SD 22.03) ns Between-group difference: ns	<u>DBT</u> EQ-5D Baseline: 57.69 (SD 21.55) 12 months: 63.84 (SD 20.47) ns	Treatment duration was 1 year Health-related quality of life was measured using EQ-5D thermometer (scale 0-100, higher better)	+	?	?
McMain 2012 Canada	RCT – single blind trial (same as above)	180	Dropouts at 36 months 70/180 (39%)	<u>GPM</u> EQ-5D Baseline: 55.29 (SD 19.41) 24 months: 63.18 (SD 20.43) 36 months: 67.69 (SD 20.97) p= 0.007 Time effect FU phase: p= 0.007 Group effect FU phase: ns	<u>DBT</u> EQ-5D Baseline: 57.69 (SD 21.55) 24 months: 64.80 (SD 21.63) 36 months: 64.31 (SD 21.12)	Both groups showed significant improvements during the follow-up phase (slope=0.29, t=2.17, df=843, p=0.007)	+	?	?

DBT: Dialectic Behavioural Therapy; FU: Follow-up; GPM: General Psychiatric Management; ns: not significant

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.6

Outcome variable: Healthcare utilisation

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
McMain Canada 2009	RCT	180	Dropped out prior to randomisation: n=25 Dropped out in FU phase: GPM: n=34 (37.8%) DBT: n=35 (38.9%)	<u>GPM</u> <u>ED visits</u> Baseline: 2.08 (3.53) 12 months: 1.00 (2.20) Time effect: OR 0.43, p=0.001 Group effect: 1.19, ns <u>ED visits for suicidal behaviour</u> Baseline: 0.77 (1.65) 12 months: 0.29 (1.13) Time effect OR: 0.35, p=<0.001 Group effect: 1.35, ns <u>Days in psychiatric hospital</u> Baseline: 8.70 (24.91) 12 months: 2.23 (6.55) Time effect OR: 0.23, p=<0.001 Group effect 1.09, ns	<u>DBT</u> <u>ED visits</u> Baseline: 1.99 (3.01) 12 months: 0.93 (1.47) <u>ED visits for suicidal behaviour</u> Baseline: 1.01 (1.47) 12 months: 0.41 (1.00) <u>Days in psychiatric hospital</u> Baseline: 10.52 (24.42) 12 months: 3.73 (14.90)	Treatment duration was 1 year	+	?	?
McMain Canada 2012	RCT (same as above)	180	Dropouts at 36 months: n=70 (39%)	<u>GPM</u> <u>ED visits</u> Baseline: 2.08 (3.53) 24 months: 0.79 (2.3) 36 months: 0.67 (1.22) Time effect: RR 0.77, ns	<u>DBT</u> <u>ED visits</u> Baseline: 1.99 (3.01) 24 months: 0.42 (0.91) 36 months: 0.68 (1.54)		+	?	?

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.6

Outcome variable: Healthcare utilisation

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
				Group effect: RR 0.82, ns <u>ED visits for suicidal behaviour</u> Baseline: 0.77 (1.65) 24 months: 0.24 (0.79) 36 months: 0.20 (0.58) Time effect: RR 0,78, ns Group effect: RR 0.42, ns <u>Days in psychiatric hospital</u> Baseline: 8.70 (24.91) 24 months: 2.69 (14.76) 36 months: 3.03 (9.56) Time effect: RR 1.17, ns Group effect: RR 0.95, ns <u>Number of psychiatric admissions</u> Baseline: 0.70 (1.23) 12 months: 0.29 (0.81) 24 months: 0.11 (0.36) 36 months: 0.42 (1.85)	<u>ED visits for suicidal behaviour</u> Baseline: 1.01 (1.47) 24 months: 0.10 (0.30) 36 months: 0.30 (1.22) <u>Days in psychiatric hospital</u> Baseline: 10.52 (24.42) 24 months: 2.14 (10.92) 36 months: 2.76 (13.27) <u>Number of psychiatric admissions</u> Baseline: 0.60 (1.15) 12 months: 0.21 (0.66) 24 months: 0.10 (0.36) 36 months: 0.22 (0.91)				

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.6

Outcome variable: Healthcare utilisation

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD), unless otherwise stated	Control Mean (SD), unless otherwise stated				
				Time effect: RR 0.77, ns Group effect: RR 1.20, ns <u>Number of psych medications</u> Baseline: 2.41 (1.94) 12 months 2.23 (1.93) 24 months: 2.04 (1.89) Δ -0.37 36 months: 2.39 (2.16) Time effect: RR 0.99, ns Group effect: RR 0.98, ns <u>Number of ps treatments</u> Baseline: 1.46 (1.17) 12 months: 0.56 (0.71) 24 months: 0.86 (0.95) 36 months: 0.93 (1.10) Time effect: RR 1.51, p=0.001 Group effect: RR 1.53, ns	<u>Number of psych medications</u> Baseline: 2.66 (1.81) 12 months: 1.58 (1.58) 24 months: 1.81 (1.72) 36 months: 1.65 (1.78) <u>Number of ps treatments</u> Baseline: 1.53 (1.35) 12 months: 0.34 (0.76) 24 months: 0.81 (0.95) 36 months: 0.76 (0.88)				

DBT: Dialectical behavioural therapy; ED: Emergency Department; FU: Follow-up; GPM: General psychiatric management; ps: psychosocial; RCT: Randomised controlled trial

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.7

Outcome variable: Disability/function

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD)	Control Mean (SD)				
McMain Canada 2009	RCT, single-blind trial	180	Dropped out prior to randomisation: n=25 Dropped out in FU phase: GPM: n=34 DBT: n=35	<u>GPM</u> <u>Interpersonal functioning (IIP-64, total score)</u> Baseline: 120.95 (37.30) 12 months: 101.58 (45.19) Time Effect Coefficient: -1.76, p=<0.001 Group Effect Coefficient: 0.36, ns Effect size 0.47	<u>DBT</u> <u>Interpersonal functioning (IIP-64, total score)</u> Baseline: 118.58 (43.85) 12 months: 100.24 (50.62)	Treatment duration 1 year Single blind Interpersonal functioning measured with Inventory of Interpersonal Problems-64, total score (IIP total). The instrument is a 64-item questionnaire that measures interpersonal distress according to the two dimensions dominance and affiliation. Patients respond to the items on a 5-point Likert scale, ranging from 0 = 'Not at all' to 4 = 'Extremely'. Higher scores indicate more interpersonal distress.	+	?	?
McMain Canada 2012				<u>GPM</u> <u>Interpersonal functioning (IPP-64, total score)</u> Baseline: 120.95 (37.30) 24 months: 97.11 (48.46) 36 months: 84.36 (45.46) Time Effect Coefficient: -0.82 (95% CI -1.19 to -0.44), p=<0.0001 Group Effect Coefficient: 0.48 (95% CI -0.07 to 1.04), ns Effect size 0.47	<u>GPM</u> <u>Interpersonal functioning (IPP-64, total score)</u> Baseline: 118.58 (43.85) 24 months: 94.93 (49.88) 36 months: 94.48 (47.96)		+	?	?
Kramer Switzerland 2014	RCT treated as case series	85	55	<u>GPM</u> <u>IIP total</u>		IIP total: Item score 0 (not at all) - 4 (very much). Global score is a mean of all items.	+	+/?	+/?

Project: General Psychiatric Management

* + No or minor problems
 ? Some problems
 - Major problems

Appendix 4.7

Outcome variable: Disability/function

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention Mean (SD)	Control Mean (SD)				
				Baseline: 1.67 (0.53) 10 weeks: 1.54 (0.65) <u>GPM+MOTR</u> <u>IIP total</u> Baseline: 1.90 (0.59) 10 weeks: 1.60 (0.61)					

DBT: Dialectic Behaviour Therapy; GPM: General Psychiatric Management; MOTR: Motive-oriented therapeutic relationship; RCT: Randomised controlled trial

Innehållsdeklaration

Denna HTA-rapport är baserad på följande moment:

<input type="checkbox"/>	Metodbeskrivning
<input type="checkbox"/>	PICO
<input type="checkbox"/>	Uttömmande litteratursökning
<input type="checkbox"/>	Flödesschema
<input type="checkbox"/>	Urval relevans
<input type="checkbox"/>	Kvalitetsgranskning
<input type="checkbox"/>	Tabelldata
<input type="checkbox"/>	Sammanvägning av resultat
<input type="checkbox"/>	Metaanalys
<input type="checkbox"/>	Evidensgradering enligt GRADE
<input type="checkbox"/>	Sammanfattning
<input type="checkbox"/>	Ekonomi
<input type="checkbox"/>	Organisation
<input type="checkbox"/>	Etik
<input type="checkbox"/>	Pågående studier
<input type="checkbox"/>	Exkluderade artiklar
<input type="checkbox"/>	Expertgrupp deltar
<input type="checkbox"/>	Extern granskning
<input type="checkbox"/>	Kunskapsluckor identifierade
<input type="checkbox"/>	Jävsdeklaration inhämtad från projektdeltagarna

