Effects of a general practitioner-led brief narrative exposure intervention on symptoms of post-traumatic stress disorder after intensive care (PICTURE): multicentre, observer blind, randomised controlled trial

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ABSTRACT

OBJECTIVE

To determine the effect of a novel brief general practitioner (GP)-led narrative exposure intervention on post-traumatic stress disorder (PTSD) symptoms after intensive care.

DESIGN

Multicentre, observer blind, randomised controlled trial (PICTURE).

SETTING

Primary care in 319 general practices across Germany.

PARTICIPANTS

319 adults (18-85 years) who have survived critical illness with symptoms of PTSD, discharged from intensive care and randomised to receive the intervention (n=160) or improved usual care (n=159) from a general practitioner.

INTERVENTIONS

Intervention group participants had three narrative exposure consultations with a general practitioner and eight scheduled contacts with a nurse. Control group participants received improved treatment as usual based on the German PTSD guideline.

MAIN OUTCOME MEASURES

The primary clinical outcome was self-reported PTSD symptoms using the Post-Traumatic Diagnostic Scale for DSM-5 (PDS-5, range 0-80, higher scores indicating more severe symptoms) at six months. The minimal clinically important difference was six points. Secondary outcomes included changes in depression, anxiety, patient activation, health related quality of life and disability at six and 12 months.

RESULTS

Between 21 October 2018 and 18 January 2023, 1283 patients discharged from an intensive care unit were screened for PTSD symptoms. 319 study participants were randomly assigned either to the control group (n=159) or the intervention group (n=160). The mean patient age was 57.7 years (standard deviation (SD) 12.7), and 61% of participants were male. The mean baseline PDS-5 score was 30.6 (SD 13.3) in both groups. 271 (85%) study participants completed follow-up assessment after six months and 247 (77%) after 12 months. The intervention effect showed a mean between-group difference in the PDS-5 score of 4.7 points ((95% confidence interval 1.6 to 7.8); P=0.003, Cohen's d=0.37)) at six months and 5.4 points ((1.8 to 9.0); P=0.003, Cohen's d=0.41)) at 12 months. Among secondary outcomes, patients in the intervention group had greater improvements in depression, health related quality of life, and disability.

CONCLUSIONS

In adults with symptoms of PTSD after critical illness, a brief narrative exposure intervention was feasible and showed a reduction of symptoms, which was less than the predefined minimal clinically important difference. The effect was found to be sustained at 12 months' follow-up. These findings support the further evaluation of this intervention in primary care.

TRIAL REGISTRATION

ClinicalTrials.gov, NCT03315390; DRKS-ID DRKS00012589

WHAT IS ALREADY KNOWN ON THIS TOPIC

Approximately one in five patients experience symptoms of post-traumatic stress disorder (PTSD) after discharge from an intensive care unit (ICU)

Most post-ICU follow-up care is provided in general practice; access to mental health services is often limited with long waiting lists

There is limited evidence on narrative exposure interventions for PTSD symptoms delivered in general practice

WHAT THIS STUDY ADDS

A novel brief narrative exposure intervention in general practice reduced PTSD symptoms in 319 patients following ICU treatment, with a result under the predefined minimal clinically important difference

The intervention was feasible to be delivered in small size general practice teams and the effect was maintained at six and 12 months' follow-up

The intervention may bridge long waiting times between ICU discharge and access to mental health services

Introduction

Advances in intensive care medicine have increased the number of patients treated in an intensive care unit (ICU) and their survival rate over the past few decades.[1 2] Approximately half of patients who have survived critical illness experience new physical, mental, or cognitive impairment, or a combination.[3] Within one year following ICU discharge, the prevalence of symptoms of post-traumatic stress disorder (PTSD) is approximately 20%, depending on factors such as psychiatric history or ICU medications.[4]

PTSD symptoms occur due to the generalisation and fusion of traumatic memories. This process results in frequent and inappropriate activation of alarm responses, sometimes triggered by subtle cues.[5] PTSD symptoms are associated with a life-threatening experience of critical illness in the ICU,[6] manifesting in somatisation, social withdrawal, or even loss of employment, resulting in a reduced health-related quality of life.[4 7] Given the prevalence of substantial PTSD symptoms and their detrimental impact on quality of life, experts have called for PTSD symptom screening and treatment after ICU admission.[8]

Psychological interventions can be effective in reducing PTSD symptoms,[9 10] but there is limited evidence on their delivery within general practice teams, where most post-ICU care is provided.[11-13] A randomised controlled trial done by our study group in German general practices did not improve overall mental health-related quality of life in people who survived sepsis after ICU discharge, possibly due to an unspecific multicomponent intervention.[14] Two randomised controlled trials of nurse-led interventions delivered at ICU departments did not prevent or improve PTSD symptoms, which the authors attributed to the following reasons: the intervention may have been too short; the intervention was offered too early, when patients still had baseline delusional memories or were too fatigued to focus on therapy; ICU nurses were inexperienced in delivering psychological treatment; and establishing an appropriate therapeutic environment at the ICU is difficult.[15 16]

Given the limited availability of mental health services in many regions,[17] brief interventions for PTSD symptoms are needed in general practice.

Narrative exposure therapy is an evidence-based treatment for traumatic stress disorders that can be delivered also by non-psychotherapists.[9 18] We designed and conducted a brief primary care version of the narrative exposure therapy for patients with PTSD symptoms after discharge from the ICU.

Methods

Study design and participants

The multicentre, observer blind, randomised controlled trial PICTURE was conducted in the German primary care setting. Patients were recruited between 21 October 2018 and 18 January 2023. The ethics committee of the Medical Faculty of LMU Munich, Germany, approved the study protocol on 20 September 2017 (approval number 17–436).

The trial protocol was published previously (eMethods 1).[19] Adjustments to the eligibility criteria were made due to emerging evidence. After discharge from ICU, patients were screened for eligibility by trained study assistants. Eligibility criteria were: age 18-85 years; any breathing support during the ICU stay; maximal sequential organ failure assessment (SOFA) score of ≥3 (adjustment after initial criteria of ≥5, according to Dijkstra-Kersten et al[20]); life expectancy of at least nine months; no cognitive impairment (six-item screener ≥4 points); and mild to moderate PTSD symptoms using the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5 score of ≥2 (adjustment after initial criteria of ≥3, according to van der Meer et al and Sager et al[21 22]), a screening tool with reasonable performance characteristics for use in general practice.[23] Inclusion criteria for PTSD symptom severity at baseline were PTSD symptoms with a score of 15-70 on the Post-Traumatic Diagnostic Scale for DSM-5 (PDS-5; adjustment after initial criteria of 20-50, according to Röhr et al[24]).

After patients were screened for eligibility, their general practice was invited to participate in the trial. General practitioners (GPs) had to be qualified by an 80 hour course in standard psychosomatic care, which is a prerequisite for general practice board certification in Germany.[25] As GPs were invited secondarily on the basis of their patients, the risk of GP preselection was low. GPs received a financial compensation (€500; £430; $552) based on time worked, equivalent to the reimbursement they would receive from the health insurance. Patients were invited for an in-person baseline assessment of their PTSD symptoms based on the PDS-5. Patients were included by the GP if their PDS-5 score was between 15 and 70. Eligible patients who scored more than 70 were not enrolled and referred directly to psychiatric care. Exclusion criteria were inability to consent; insufficient understanding of the German language; severe physical or mental illness incompatible with regular study participation; life expectancy of less than nine months; ongoing addiction disorders; severe depressive symptoms (Patient Health Questionnaire-9; PHQ-9 score of ≥23); acute suicide risk; concomitant trauma-based psychotherapy for PTSD; or high-dose antipsychotic, anticholinergic, or anticonvulsive medication for psychiatric indications. Consenting patients were randomly assigned in a 1:1 ratio to the intervention or to the improved usual care group using a web-based randomisation software,[26] which generated randomly permutated sequences to minimise imbalances. Each GP had only one enrolled patient. Due to the nature of the trial design, randomisation status was disclosed to GP teams and patients without masking. Assessors of the outcomes were masked.

Intervention

Narrative exposure therapy, adapted for general practice, is a trauma-focused intervention that uses storytelling to reconsolidate the autobiographical memory,[10 27] which has shown clinical effectiveness in multiple settings.[28] Constructing an illness narrative for patients who have been in an ICU helps to integrate fragmentary memories in their own life history and to realise what really happened during their ICU stay.[29 30] These mechanisms are known to reduce PTSD symptoms.[31-33] GPs and practice nurses of patients randomly assigned to the intervention group received a treatment folder, GP manual, nurse manual (30-45 minutes for home study time each;). Patients in the intervention group received a patient manual from their caring GPs. GPs and practice nurses were trained

individually by a psychologist from the research team. One-on-one training for GPs (60-90 minutes, either face-to-face or virtual, including practical exercises) focused on diagnosing PTSD and delivering narrative exposure therapy. This training did not include individualised advice for the specific patient being treated. Nurses received group training focused on monitoring patients' PTSD-related symptoms (60 minutes, either face-to-face or virtual). Patients in the intervention group had three personal consultations with their GPs in their practice with a planned duration of 45 minutes each. The first consultation addressed psychoeducation on PTSD; GPs and patients also collaboratively developed a chronological narrative of the patient's major life experiences. In the second consultation, the patient re-experienced the traumatic experience in the ICU through imaginary exposure based on their narration. Arousing emotions, physiological responses, and cognitive patterns were contextualised to the safe presence . After the second consultation, the study psychologist met with the GP for a virtual follow-up call of 20 minutes to check the feasibility of the intervention and to reinforce the initial training.

In the third consultation, GPs and patients either repeated the exposure to the ICU experience or focused on another previous traumatic experience. The primary care nurses completed a PTSD monitoring checklist by performing two phone calls (15 minutes) with the patient between the second and third consultations, as well as five weekly phone calls after the third consultation. In the event of symptom worsening recorded by the nurses, the GP was immediately informed and an additional consultation was scheduled.

Control

Usual care of post-traumatic symptoms in Germany is focused on early recognition, stabilisation, and psychoeducational support. In the case of severe symptoms, referral to psychiatric service is recommended.[34] All GPs and involved practice nurses of both groups received a general manual, including basic information about diagnosis and treatment of PTSD based on the German treatment guideline for PTSD.[34] As in the intervention group, GPs randomly assigned to the control group were instructed to provide three consultations focused on PTSD symptoms with a duration of 45 minutes each. Thus, patients randomly assigned to the control group received improved treatment as usual.

Data collection and outcome measures

Trained study staff used the PC-PTSD-5 to screen patients up to 24 months after ICU discharge to identify eligible patients.[35] At enrolment and at six and 12 months after randomisation, study staff masked to allocation assessed patient-reported symptoms during a telephone interview.

The primary outcome was the absolute change in PTSD symptom severity from baseline to six months, using the total score of the PDS-5, which has 20 items with a five-point Likert scale and a score range of 0-80 points, with higher scores indicating more severe symptoms. The minimal clinically important difference was defined as six points.

Secondary outcomes included changes at six and 12 months in depression, anxiety, patient activation, health-related quality of life and disability, as well as the absolute change in PTSD symptoms from baseline to 12 months. PTSD symptoms were assessed by the PDS-5;[36] depressive symptoms by thePHQ-9, which has nine items, score range 0-27;[37] anxiety by the Overall Anxiety Severity and Impairment Scale (OASIS), which has five items, score range 0-20[38]; self-efficacy by the Patient Activation Measure (PAM), which has 13 items, score range 13-52[39]; and quality of life by EQ-5D-5L index score (EQ-5D-5L), score range 0-1, and the single-item EQ-5D-5L Visual Analog Scale (EQ-VAS), score range 0-100[40]; disability by the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0), score range 0-100.[41] For all instruments, higher scores reflect greater or worse symptom burden, except for the EQ-5D-5L and EQ-VAS, where higher scores reflect better quality of life.

The numbers and dates of consultations were captured in the final visit form. Sufficient treatment adherence was defined as provision of three consultations of at least 45 minutes. To assess the feasibility (barriers and facilitators) of the intervention from the perspective of the general practice team, GPs in the intervention group participated in semi-structured follow-up interviews of approximately 20 minutes with the study psychologist. Interview protocols were analysed using dimensions of the Capability, Opportunity, and Motivation-Behaviour (COM-B) model.[42]

Missing data

Questionnaires with less than a third of missing items were completed by imputation using chained equations with age, gender, education, and main International Classification of Diseases, 10th Revision (ICD-10) diagnosis included as covariates in the imputation model. This applied to fewer than 5% of observations for all outcomes, except for PDS-5 at six (10.7%) and 12 months (11.7%). Questionnaires with more than a third of missing items were considered as missing. To account for potentially informative missingness resulting from study dropout, we used a logistic model for study completion. We adjusted this model for treatment randomisation, age, gender, education, and main ICD-10 diagnosis at ICU, to derive stabilised inverse probability weights for adjustment of multivariable regression models.

Statistical analysis

The statistical analysis plan for this trial was previously published (ClinicalTrials.gov, NCT03315390; eMethods 2). The primary efficacy endpoint was the between-group difference in mean change in PDS-5 from baseline to six months. This was calculated as

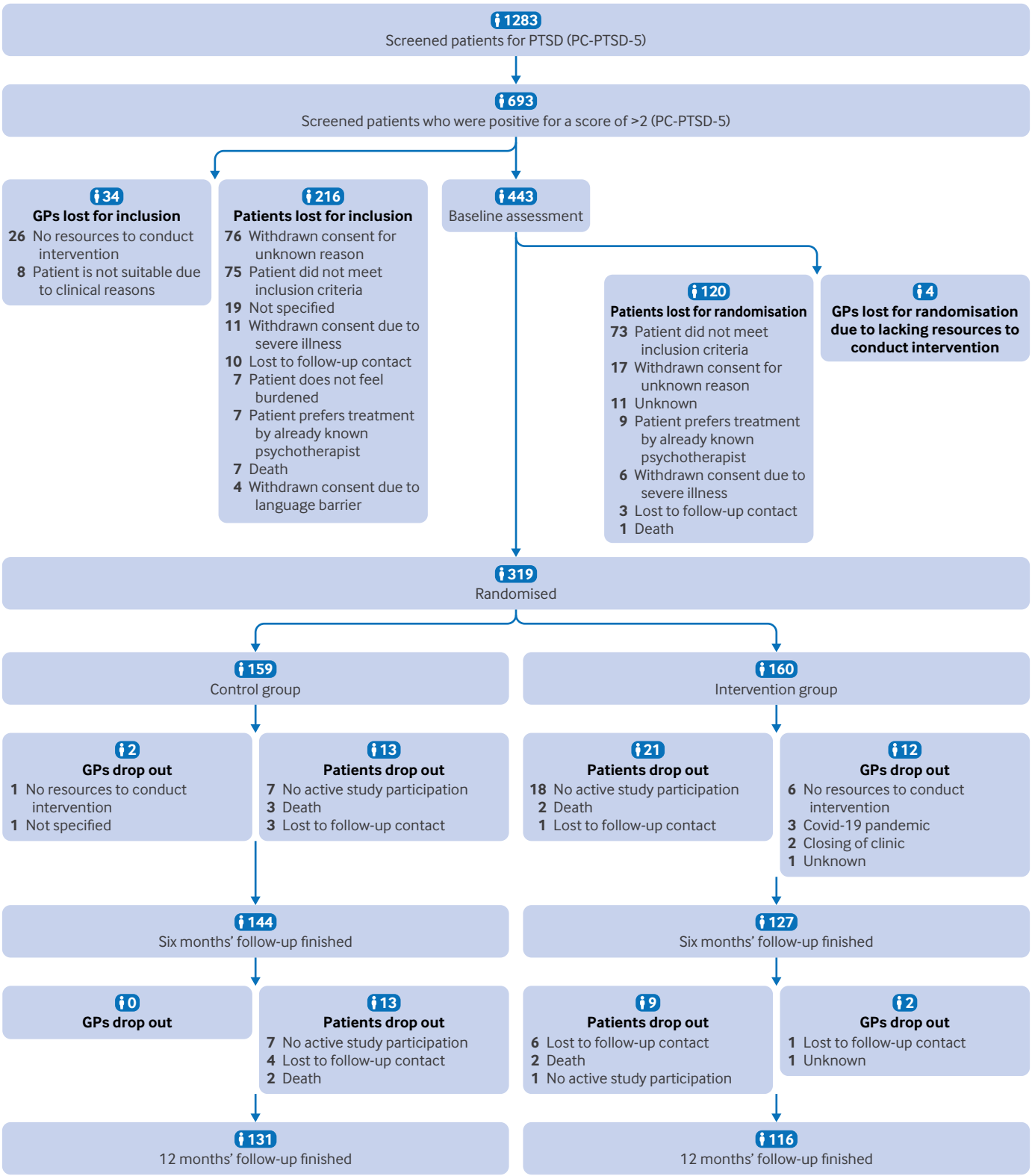

Fig 1 | CONSORT flow chart

the difference between the PDS-5 scores six months after randomisation and at baseline using a two sample t-test and Cohen's d under the intention-to-treat principle. We additionally assessed response (>50% improvement in the PDS-5 score[43] and remission from probable PTSD (symptom reduction in patients with PDS-5 ≥36 points at baseline).[44] For sensitivity analysis, we fit a series of generalised linear regression models for each outcome with Gaussian family and identity link functions and robust standard

errors. Models were adjusted for baseline symptom score, sociodemographic factors (ie, age, gender, education), worst SOFA score in ICU, with applied stabilised inverse probability weights to account for study dropout. To elucidate the treatment mechanism, subscales of the PDS-5 score (intrusion, avoidance, mood and cognition, arousal, and distress) were transformed to z-scores and standardised to baseline mean to compare effect sizes across the subscales, and then also analysed using generalised linear regression models. Statistical analyses were performed using Stata 15.1 (Stata Corp, College Station, TX, USA).

Patient and public involvement

The study design took into account the needs of different stakeholders, based on evidence from a primary care management intervention on mental health-related quality of life in people who had

Table 1 | Baseline characteristics of the study population

Sample characteristics	Control group (n=159)*	Treatment group (n=160)*
Sociodemographic data		
Male gender, no. (%)	102 (64.2)	92 (57.5)
Age (years) at baseline, mean (SD)	57.6 (13.2)	57.8 (12.2)
Age group in years, no. (%)		
18-29	4 (2.5)	4 (2.5)
30-39	12 (7.5)	10 (6.2)
40-49	20 (12.6)	20 (12.5)
50-59	52 (32.7)	53 (33.1)
60-69	40 (25.2)	47 (29.4)
≥70	31 (19.5)	26 (16.2)
Education (CASMIN levels†), no. (%)		
Low 1a-1c	43 (27.0)	41 (25.6)
Intermediate 2a-2c	56 (35.2)	79 (49.4)
High 3a-3b	51 (32.1)	34 (21.2)
N/A	9 (5.7)	6 (3.8)
Currently working	73 (45.9)	77 (48.1)
Medical data		
Principal ICD-10 diagnosis of ICU admission, no. (%)		
I (Cardiovascular disease)	68 (42.8)	61 (38.1)
J (Respiratory disease)	19 (11.9)	25 (15.6)
U (Other: Covid-19)	12 (7.5)	11 (6.9)
C (Neoplasms)	9 (5.7)	13 (8.1)
K (Gastrointestinal disease)	4 (2.5)	15 (9.4)
Other	47 (29.6)	35 (21.9)
Type of ICU admission, no. (%)		
Emergency	51 (32.1)	45 (28.1)
Postoperative care	86 (54.1)	93 (58.1)
Transfer	19 (11.9)	18 (11.2)
N/A	3 (1.9)	4 (2.5)
SOFA score, median (IQR)	9 (7.0-12.0)	9 (7.0-12.0)
ICU treatment duration (days), median (IQR)	7 (4-19)	8 (4-18)
Mechanical ventilation duration (days), median (IQR)	4 (2-12)	5 (2-13)
Polypharmacy (≥5 medications), no. (%)	98 (61.6)	90 (56.2)
Concomitant antidepressant therapy, no. (%)	23 (14.5)	15 (9.4)
Concomitant psychotherapy therapy, no. (%)	29 (18.2)	28 (17.5)
Outcomes at baseline		
PDS-5 score (total), mean (SD)	30.7 (13.2)	30.4 (13.4)
Probable PTSD (PDS-5 score ≥36)	54 (34.0)	52 (32.5)
Previous traumatisation‡	11 (6.9)	12 (7.5)
PHQ-9 score, mean (SD)	9.5 (4.8)	9.6 (4.8)
Depression (PHQ-9 ≥10)	82 (51.6)	76 (47.5)
OASIS score, mean (SD)	6.6 (4.6)	6.2 (4.5)
Anxiety (OASIS ≥8), no. (%)	67 (42.1)	61 (38.1)
PAM score, mean (SD)	41.8 (6.2)	41.7 (5.7)
EQ-5D-5L VAS, mean (SD)	60.5 (18.9)	61.0 (19.9)
EQ-5D-5L Index value, median (IQR)	0.8 (0.6-0.9)	0.8 (0.5-0.9)
WHODAS 2.0 score, median (IQR)	9.2 (5.4-15.2)	9.8 (4.3-16.3)

*Missing data unless specified as not available: SOFA score (15%), ICU treatment duration (2%), breathing support duration (12%), EQ-5D-5L VAS (<1%), WHODAS 2.0 score (<1%)
†CASMIN levels according to Brauns et al.[49]
‡Assessed by PDS-5, reported (classes of) lifetime trauma
CI=confidence interval; EQ5D (VAS)=EuroQoL (visual analogue scale) for health-related quality of life, score 0-100; EQ-5D-5L Index value for health-related quality of life, score 0-1; ICD=International Classification of Diseases; ICU=intensive care unit; IQR=interquartile range; N/A=not available; OASIS=Overall Anxiety Severity And Impairment Scale for anxiety, score 0-20; PAM=Patient Activation Measure for patient involvement, score 13-52; PDS-5=Post-Traumatic Diagnostic Scale 5 for PTSD, score 0–80; PHQ-9=Patient Health Questionnaire-9 for depression, score 0-27; PTSD=post-traumatic stress disorder; SD=standard deviation; SOFA=Sequential Organ Failure Assessment; WHODAS 2.0=World Health Organization Disability Assessment Schedule, for disability, score 0-100.

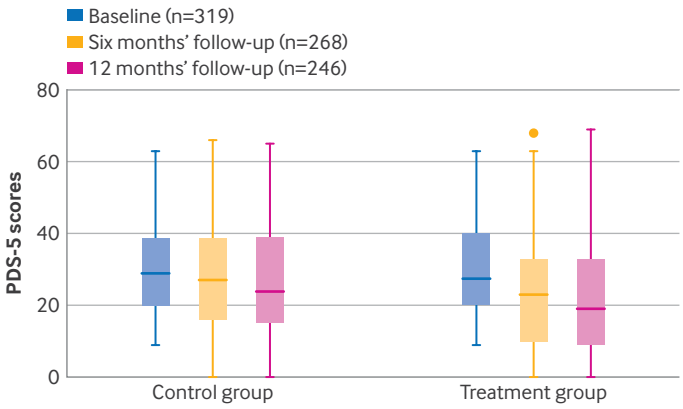

Fig 2 | Boxplots for the main outcome of change in PDS-5 by treatment group at baseline, six, and 12 months' follow-up. Boxes indicate median and interquartile range, whiskers indicate range, y axis shows PDS-5 sum scores. PDS-5=Post-Traumatic Diagnostic Scale 5 for post-traumatic stress disorder, score 0-80

sepsis, and feedback from patient representatives of the German Sepsis Aid patient organisation.[14] The experiences of participating patients and healthcare teams were assessed using semi-structured interviews on facilitators and barriers.[45 46] The overall outcome of this pre-intervention patient and public involvement was the need for more intervention intensity and specificity.

Subsamples of patients and GPs were interviewed using semi-structured questionnaires during and after this intervention. High acceptance by both GPs and patients was shown, with feedback on the challenges of integration into daily GP practice.[47 48] The longitudinal and structured patient and public involvement allowed for a complex study in the highly fragmented setting of German general practice. However, it would have been beneficial to evaluate the perspectives of eligible patients and GP teams who chose not to participate.

Results

Among 1283 patients discharged from a study ICU and screened for PTSD symptoms, 693 (54%) were eligible. Of these, 443 (64%) patients were assessed at baseline, of which 120 (28%) patients had to be excluded (fig 1). 319 (72%) patients were randomly assigned to intervention versus control, at a median of seven months (212 days; interquartile range (IQR) 135-376) from ICU discharge.

Twenty six GPs declined to participate before baseline assessment due to lack of resources, eight GPs assessed their patient as not suitable due to clinical reasons, and four GPs withdrew their willingness to participate after baseline assessment.

Baseline characteristics

The mean patient age was 57.7 years (SD 12.7) and 60.8% were male. Most patients (56%) were admitted to the ICU for postoperative care. The median length of ICU stay was seven days (IQR 4-19) and the median SOFA score was nine (IQR 7-12). The mean baseline PDS-5 score was 30.6 (SD 13.3) and 106 (33.2%) patients had a score of at least 36, consistent with a probable diagnosis of PTSD. Nearly half (49.5%) had comorbid depression, and about 40% suffered from comorbid anxiety, based on established cut-off values (PHQ-9 ≥10 and OASIS ≥8). The median EQ-VAS was 60 (IQR 50-75). Patients had moderate disability, with a median WHODAS 2.0 score of 9.8 (IQR 4.3-16.3). Measured characteristics between the intervention and control groups were balanced at baseline (table 1).

Baseline characteristics of GPs in both groups were similar (supplementary table S1).

At six months, 271 (85%) patients completed follow-up assessment, 48 (15%) patients and 14 (4.4%) GPs dropped out before the six months follow-up. Of these, more participants were in the intervention group (33 (68.8%) patients; 12 (3.8%) GPs) than in the control group (15 (31.2%) patients; P=0.005; two (0.6%) GPs).

Intervention delivery

Most patients received three therapeutic consultations with their GPs as intended (90.6% of all patients in the intervention group, compared with 81.2% in the control group). The median of consultation times was 55 minutes (IQR 45-60), (supplementary table S2). Nearly all GPs (94.5%) addressed the patient's

Table 2 | Mean differences (standard deviation) (95% confidence interval), unless otherwise specified, at six months' follow-up

	Control group (n=144)		Intervention group (n=127)			
Outcome and measurement	Outcome	No. of participants	Outcome	No. of participants	Difference	P value
PTSD; PDS-5	−1.5 (12.9) (−3.6 to 0.6)	143	−6.2 (12.8) (−8.5 to −4.0)	125	4.7 (1.6 to 7.8)	0.003
Response (>50% improvement)	18 (12.5%)	—	35 (28.0%)	—	—	0.002
Remission from probable PTSD	—	17/44 (39%)	—	18/40 (45%)	—	0.66
Depression; PHQ-9	−0.2 (4.8) (−1.0 to 0.6)	136	−1.9 (4.4) (−2.7 to −1.2)	126	1.7 (0.6 to 2.8)	0.003
Anxiety; OASIS	−0.5 (4.4) (−1.3 to 0.2)	137	−1.0 (4.9) (−1.9 to −0.2)	125	0.5 (−0.6 to 1.6)	0.40
Patient activation; PAM	0.9 (6.5) (−0.2 to 2.0)	137	1.2 (6.0) (0.1 to 2.3)	126	−0.3 (−1.8 to 1.2)	0.70
Health-related quality-of-life; EQ5D index	0.03 (0.24) (−0.02 to 0.07)	137	0.06 (0.26) (0.02 to 0.11)	126	−0.04 (−0.1 to 0.02)	0.22
Health-related quality-of-life; EQ5D VAS	−0.3 (19.5) (−3.6 to 3.0)	137	4.7 (21.9) (0.8 to 8.6)	126	−5.0 (−10.0 to 0.0)	0.051
Disability; WHODAS 2.0	−0.5 (5.9) (−1.5 to 0.5)	137	−1.5 (6.7) (−2.6 to −0.3)	126	1.0 (−0.5 to 2.5))	0.20

Student's t-test for continuous variables, Fisher's exact test for categorical variables. 95% confidence intervals in brackets.
EQ5D (VAS)=EuroQoL (visual analogue scale) for health-related quality of life, score 0-100; EQ-5D-5L Index value for health-related quality of life, score 0-1; OASIS=Overall Anxiety Severity And Impairment Scale for anxiety, score 0-20; PAM=Patient Activation Measure for patient involvement, score 13-52; PDS-5=Post-Traumatic Diagnostic Scale 5 for PTSD, score 0-80; PHQ-9=Patient Health Questionnaire-9 for depression, score 0-27; PTSD=post-traumatic stress disorder; SD=standard deviation; WHODAS 2.0=World Health Organization Disability Assessment Schedule, for disability, score 0-100

Table 3 | Mean differences (standard deviation) (95% confidence interval), unless otherwise specified, at 12 months' follow-up

	Control group (n=131)		Intervention group (n=116)			
Outcome; measurement	Change in outcome	No. of participants	Change in outcome	No. of participants	Difference	P value
PTSD; PDS-5, mean (SD)	−2.5 (15.0) (−5.1 to 0.1)	130	−7.9 (13.4) (−10.3 to −5.4)	116	5.4 (1.8 to 9.0)	0.003
Response (>50% improvement)	30 (23.1%)	—	39 (33.6%)	—	—	0.088
Remission from probable PTSD	—	17/39 (44%)	—	18/36 (50%)	—	0.65
Depression; PHQ-9, mean (SD)	−0.2 (5.1) (−1.1 to 0.7)	128	−2.1 (4.6) (−2.9 to −1.2)	115	1.8 (0.6 to 3.1)	0.003
Anxiety; OASIS, mean (SD)	−1.4 (5.1) (−2.2 to −0.5)	128	−1.5 (5.1) (−2.5 to −0.6)	115	0.2 (−1.1 to 1.5)	0.81
Patient activation; PAM, mean (SD)	0.9 (6.6) (−0.3 to 2.0)	129	1.6 (6.4) (0.5 to 2.8)	115	−0.8 (−2.4 to 0.9)	0.35
Health related quality of life; EQ5D index, mean (SD)	0.02 (0.27) (−0.03 to 0.07)	129	0.11 (0.23) (0.07 to 0.15)	116	−0.09 (−0.16 to −0.03)	0.004
Health related quality of life; EQ5D VAS, mean (SD)	0.7 (21.3) (−3.0 to 4.4)	129	3.1 (22.0) (−1.0 to 7.1)	116	−2.4 (−7.8 to 3.1)	0.39
Disability; WHODAS 2.0, mean (SD)	−0.3 (6.5) (−1.4 to 0.8)	129	−2.2 (6.3) (−3.4 to 1.1)	116	1.9 (0.3 to 3.5)	0.019

Student's t-test for continuous variables, Fisher's exact test for categorical variables. 95% confidence intervals in brackets.
EQ5D (VAS)=EuroQoL (visual analogue scale) for health-related quality of life, score 0-100; EQ-5D-5L Index value for health-related quality of life, score 0-1; OASIS=Overall Anxiety Severity And Impairment Scale for anxiety, score 0-20; PAM=Patient Activation Measure for patient involvement, score 13-52; PDS-5=post-Traumatic Diagnostic Scale 5 for PTSD, score 0-80; PHQ-9=Patient Health Questionnaire-9 for depression, score 0-27; PTSD=post-traumatic stress disorder; SD=standard deviation; WHODAS 2.0=World Health Organization Disability Assessment Schedule, for disability, score 0-100.

biography and the traumatic ICU experience during the first two consultations. In the third consultation, 66.4% of the GPs and their patients focused on ICU or disease related burdening experiences.

Serious adverse events

In total, 34 serious adverse events were noted: 20 in the control group and 14 in the intervention group. An exacerbation of depressive symptoms following the second intervention session was possibly related to the intervention[50]; the intervention was stopped, the patient was referred to psychiatric care.

Effects on outcome measures

At six months, the mean PDS-5 score (the primary outcome) declined by 6.2 points (95% confidence interval (CI) −8.5 to −4.0) in the intervention group versus 1.5 points (−3.6 to 0.6) in the control group. The between-group difference was 4.7 points ((95% CI 1.6 to 7.8); P=0.003, Cohen's d=0.37), below the minimal clinically important difference of six points. Thirty five (28.0%) patients in the intervention group had a response in PTSD symptoms, meaning a reduction of >50% of PTSD symptoms versus 18 (12.5%) patients in the control group, P=0.002 (fig 2). Eighteen patients (45%) of 40 showed a remission from probable PTSD in the intervention group and seventeen patients (39%) of 44 in the control group, P=0.66 (table 2).

At 12 months follow-up, 247 (77%) patients completed the assessment. The between- group difference in the PDS-5 score showed a sustained treatment effect of 5.4 points ((95% CI 1.8 to 9.0); P=0.003, Cohen's d=0.41). Among secondary outcomes, patients in the intervention group had greater improvements in depression (PHQ-9), disability (WHODAS-2.0), and quality of life (EQ-5D-5L) (table 3).

The sensitivity analysis shows multivariable regression models of the primary and secondary outcome scores at six months (table 4). The intervention effects were deemed to be robust to adjustment for potential confounders (baseline severity, gender, age, education, and SOFA score), thus verifying the effect sizes (supplementary table S3). When using raw scores without imputation, no meaningful differences were noted for the primary outcome (PDS-5 score −1.8 *v* −6.3 at six months, P=0.006; −2.8 *v* −7.8 at 12 months, P=0.006). Regression models of the PDS-5 subscales showed a significant improvement in the subscales of intrusion, mood and cognition, and distress (fig 3).

Concomitant use of antidepressants (12% at baseline) slightly decreased in the intervention group at six months and increased in the control group (7.9% *v* 17.4%, P=0.028). Concomitant psychotherapy (18% at baseline) did not differ between groups at baseline and at both six and 12 months follow-up (supplementary table S4).

Barriers and facilitators

Ninety three (58%) GPs in the intervention group participated in follow-up interviews. Forty eight (52%) of the GPs surveyed reported time constraints and lack of resources as implementation barriers.[51] Nevertheless, nearly half (47%) considered the intervention to be feasible in routine care.[52] GPs recognised that an initial investment of time for training may save time in the longer term, as patients with PTSD symptoms often present to primary care providers for somatisation disorders.[53]

Discussion

Principal findings

In this multicentre trial, 319 people who survived critical illness with mild to moderate PTSD symptoms were treated in general practice. Results showed that a brief GP-led narrative exposure intervention was feasible and reduced PTSD symptoms compared with improved usual care. The effect was found to be sustained at six and 12 months follow-up. No relevant incidence of adverse events was reported from the intervention.[54]

Despite relevant response rates, the observed between-group difference in PDS-5 scores (4.7 points)

Table 4 | PDS-5 subscales: regression models at six months' follow-up

Change in PDS-5	Total	Intrusion	Avoidance	Mood and cognition	Arousal	Distress*
Simple model						
Intervention	−0.35*** (−0.57 to −0.12)	−0.36*** (−0.59 to −0.13)	−0.12 (−0.34 to 0.11)	−0.32*** (−0.52 to −0.12)	−0.18 (−0.41 to 0.06)	−0.26** (−0.48 to −0.04)
Baseline score	0.73*** (0.62 to 0.84)	0.58*** (0.46 to 0.69)	0.45*** (0.34 to 0.56)	0.57*** (0.48 to 0.66)	0.69*** (0.58 to 0.81)	0.56*** (0.46 to 0.67)
Full model						
Intervention	−0.34*** (−0.56 to −0.11)	−0.34*** (−0.56 to −0.11)	−0.10 (−0.33 to 0.12)	−0.33*** (−0.53 to −0.13)	−0.16 (−0.40 to 0.07)	−0.26** (−0.47 to −0.05)
Gender (male)	0.02 (−0.21 to 0.26)	0.12 (−0.12 to 0.36)	0.03 (−0.21 to 0.26)	−0.11 (−0.32 to 0.11)	0.05 (−0.19 to 0.29)	0.10 (−0.13 to 0.32)
Age (years)	−0.01* (−0.02 to 0.00)	−0.01* (−0.02 to 0.00)	−0.01 (−0.01 to 0.00)	−0.00 (−0.01 to 0.00)	−0.01* (−0.02 to 0.00)	−0.01 (−0.01 to 0.00)
Education	−0.12 (−0.28 to 0.03)	−0.13 (−0.29 to 0.03)	−0.16** (−0.31 to −0.01)	−0.08 (−0.22 to 0.07)	−0.16* (−0.33 to 0.00)	−0.28*** (−0.42 to −0.13)
SOFA score	0.04** (0.01 to 0.07)	0.04** (0.01 to 0.07)	0.01 (−0.02 to 0.04)	0.01 (−0.01 to 0.04)	0.04*** (0.01 to 0.07)	0.03* (−0.00 to 0.06)
Baseline score	0.73*** (0.62 to 0.84)	0.57*** (0.45 to 0.68)	0.44*** (0.33 to 0.55)	0.57*** (0.48 to 0.66)	0.71*** (0.59 to 0.83)	0.55*** (0.44 to 0.66)

*P<0.1, **P<0.05, ***P<0.01.
N=268. Subscales standardised to z scores. General linear model with 95% confidence intervals in parentheses. PDS-5=Post-Traumatic Diagnostic Scale 5 for post-traumatic stress disorder, score 0-80; SOFA=sequential organ failure assessment

was below the minimal clinically important difference of six points defined in the protocol. This finding may be related to the low intensity of our intervention with only three sessions, which limits a substantial symptom reduction.

The intervention showed a positive effect on health-related quality of life and disability, even after 12 months, highlighting the broader impact of PTSD symptom reduction on patient wellbeing.[55]

Treatment adherence and feasibility

The intervention was delivered according to the protocol in the vast majority of cases (eg, 90.6% GPs within the intervention group have completed three requested consultations). In addition, a large number of GPs was enrolled with low dropout rates (after six months, 14 (4.3%) GPs dropped out), even though more than half of the GPs worked in underserved, non-urban areas with high workloads. The enrolment procedure (first the patient, then their GP) reduced the likelihood of selection bias towards pro-active and highly motivated GPs.

Patients after critical illness face many burdens, resulting in high dropout rates in clinical trials. The overall dropout rate in our cohort was lower than in other post-ICU trials,[56] also lower than that reported in meta-analyses of 85 (20.9%), respectively115 randomised controlled trials (16%) of psychological interventions for PTSD [57 58] and similar to other primary care mental health trials.[59] This may be related to the short and simple design of the intervention.

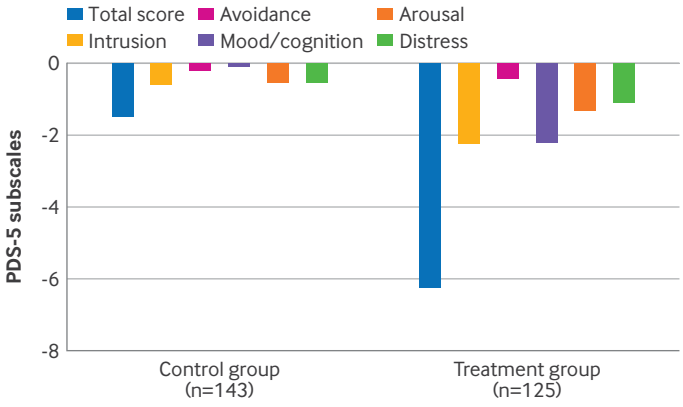

Fig 3 | Mean change between baseline and six months' follow-up for PDS-5 subscales. X axis shows differences in PDS-5 subscale scores. PDS-5=Post-Traumatic Diagnostic Scale 5 for post-traumatic stress disorder, score 0-80

Comparison with other studies

The effect size (0.37) was smaller than that found in a meta-analysis of seven narrative exposure therapy interventions on refugees (0.53).[60] However, these interventions targeted patients diagnosed with clinical manifest PTSD (eg, according to DSM-IV/V, ICD-10) at baseline and used a higher number of consultations (4-16 trauma-focused individual sessions). In addition, meta-analyses of PTSD interventions found reduced effect sizes for studies with active control groups and an effect size similar to our study (Hedges' g=0.42) for 10 PTSD interventions with at least 12 months' follow-up.[61] Our response rate was similar to other psychological interventions in general practice.[62]

PTSD symptoms were still improved at the 12 months' follow-up, six months after intervention delivery, which is similar to the results from more intensive interventions on PTSD.[63 64] Unlike psychotherapy in specialist mental health settings, which often requires additional time to develop a therapeutic relationship between provider and patient,[65] the intervention may benefit from continuity in the patient's relationship with the general practice team and a trusting therapeutic environment,[66] which are associated with improved clinical outcomes.[67]

Our analysis of the PDS-5 subscales showed an improvement in the domains intrusion, mood and cognition, and distress, but not avoidance or hyper-arousal (table 4). We hypothesise that the intervention's mechanism of action possibly reduced PTSD-related intrusions and thereby improved PTSD-related mood and cognition.[68] This may have had a positive impact on such secondary outcomes as depression, health related quality of life, and disability. In contrast to psychological interventions with more consultations

on PTSD,[63 64] our intervention did not reduce patients' defence mechanisms against traumatic stimuli (avoidance behaviour) and stress-related agitation (hyper-arousal).

Implications for clinicians and policy makers

As patients are frequently delirious and may be unaware of their situation during their stay in the ICU, whether they benefit from psychological interventions in the ICU setting or shortly after is not known.[16] Existing interventions based on ICU diaries or ICU specialist follow-up clinics show heterogeneous results.[69-73] According to the diagnostic criteria, PTSD symptoms must have been present for more than one month.[59] In most cases, subthreshold PTSD symptoms are present from the time of the traumatic event until the diagnosis of manifest PTSD.[74] In addition, delayed onset PTSD symptoms that are not detected during an ICU stay have been found in about a quarter of patients after an ICU discharge.[75] Thus, the timing of the intervention on average at three months after ICU stay may adequately address emerging symptoms and prevent more severe outcomes.

Patients with PTSD show mostly non-specific symptoms such as sleep disturbance, exhaustion, feelings of guilt, or depressive symptoms,[76] and rarely seek psychological support.[77] After discharge from the ICU and hospital, general practices provide continuous and reliable service to the patient.[66] In addition, access to mental health specialist services is often limited.[78] Our intervention may bridge the burdening time spent on a waiting list for mental health specialists, which is up to 23 weeks in certain UK areas and about 20 weeks in Germany.[79-81] Thus, participating GPs emphasised the benefits of the intervention for their patients with traumatic experiences. Professional training and follow-up calls were seen as crucial here. Training may become more effective as more patients are treated. In Germany, other primary care interventions have been integrated into usual care after showing cost-effectiveness.[82]

Study limitations

Several limitations should be considered. PTSD symptom assessments in our study used brief patient reported outcome measures rather than clinical interviews by psychological or psychiatric specialists, and therefore do not provide a definitive confirmation of a PTSD diagnosis. However, this intervention is explicitly not designed primarily to treat psychiatrically confirmed PTSD, but rather to address PTSD symptoms in general practice when access to specialist mental health services is limited.

Additionally, while the fully adjusted treatment effect is robust and closely aligns with the raw change, residual effect modification by PTSD severity cannot be fully ruled out.

Finally, the moderate baseline symptom burden and exclusion of severe cases (PDS-5 >70) limit the generalisability of our findings to individuals with manifest and more severe PTSD.

Unanswered questions and future research

Although these results are focused on survivors of critical illness, the intervention may be supportive to patients with other traumatic experiences, who make up a relevant proportion in general practice.[83]

Conclusion

This novel brief primary care-based narrative exposure intervention was feasible and reduced PTSD symptoms among survivors of critical illness. The effect did not meet the predefined minimal clinically important difference. Given the prevalence of PTSD symptoms following critical illness, and the long waiting lists for mental health specialist's service, the intervention may be feasible and beneficial for general practice.

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Contributors: JG and KFRS share first authorship. JG has full access to all study data and takes responsibility for their integrity and accuracy of the data analysis. JG, KFRS, TE, and MS were involved in the concept and design. DL, RPK, LS, JG, U-DR, TE, MS, AB, CF, JD, KFRS, and CH participated in the acquisition, data analysis, and interpretation of data. JG, LS, RPK, HCP, KFRS, and TE contributed to drafting the manuscript. JG, KFRS, LS, RPK, CF, AB, JD, CH, HCP, U-DR, MS, DL, CB, TD, BZ, and TE were responsible for the critical revision of the manuscript for important intellectual content. RPK, U-DR, and JG handled the statistical analysis. JG, TE, and KFRS obtained funding. JD, DL, and LS provided administrative, technical, and material support. JG, TE, MS, CH, and KFRS supervised the project. JG was the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/disclosure-of-interest/ and declare: all authors had financial support from the German Research Foundation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: The ethics committee of the Medical Faculty of LMU Munich, Germany, approved the study protocol on 20 September 2017 (approval number 17–436) covering all participating sites. All methods were performed in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participating GPs and patients prior data collection.

Data sharing: The analytical dataset, which includes de-identified patient data, and the code used to prepare and analyse the data, is available in the research data repository of the Ludwig-Maximilians-University of Munich "Open Data LMU" and can be accessed at https://data.ub.uni-muenchen.de/557/. Access to the dataset is subject to our data use agreement, and further details can be found in the repository documentation. For enquiries about data use, potential collaborations or related projects, interested researchers are encouraged to contact the principal investigator of the study.

Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: Preliminary results of the trial were communicated to participating GPs and their patients through a layman's leaflet. Study issues were disseminated to the general public through the press and radio. Final results will be disseminated widely to reach both academic and non-academic audiences and will be presented at national and international conferences to inform the wider medical community. All published papers from the trial will be hyperlinked to the trial centres' websites, and participating GPs will be encouraged to follow the results there. Meetings with relevant stakeholders will be organised to share and explain our findings.

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Web appendix: eMethods 1: clinical trial protocol
Web appendix: eMethods 2: statistical analysis plan