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Talking about premature ejaculation in primary care: the GET UP cluster randomised controlled trial

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ABSTRACT

Background: Premature ejaculation is the most common sexual dysfunction in men. A previous qualitative study identified six communication strategies described by general practitioners (GP) to tackle this topic during consultations.

Aim: To determine whether these six strategies are more effective than usual care for promoting discussion about premature ejaculation by patients with their GP.

Design and Setting: Cluster randomised controlled trial, stratified in four French regions, with an intervention group (GPs who received a training session on the six communication strategies) and a control group (routine medical care). Participants were 18-80-year-old men consulting for a sexual, urogenital or psychological reason.

Method: The efficacy of the training session in communication skills, compared with usual care, was evaluated by determining the percentage of patients who discussed premature ejaculation with their GP (primary outcome). The percentage of enrolled patients with premature ejaculation was calculated using as cut-off a score >9 of the Premature Ejaculation Diagnostic Tool filled in by the enrolled patients at week 4 after the consultation. The quality-of-life changes were evaluated as the SF-12 scale score difference between baseline and week 4 post-consultation.

Results: 130 patients were included by 32 GPs (n=16 in the intervention and n=16 in the control group). The percentage of patients who discussed about premature ejaculation was higher in the intervention than in the control group (42% vs. 4.9%, absolute difference = 37% 95%CI [24% to 50%], p <0.001).

Conclusions: Training GPs in communication strategies about premature ejaculation improves its detection.

Keywords: premature ejaculation, general practice, sexual dysfunction

ClinicalTrials.gov: NCT02378779, date of registration: 03/02/2015

How this fits in

- Premature ejaculation (PE) is the most frequent sexual complaint in men (21-30% of 18 to 80-year-old men), and General Practitioners (GP) are the first health professionals with whom patients discuss PE.
- PE was discussed more often by patients followed by GPs who underwent training on communication strategies on PE (intervention group) than by GPs who did not (control group): 42% versus 5% of patients with PE, respectively, $p<0.001$.
- Our results indicate that communication strategies on PE are useful in the naturalistic settings of primary care.
- The quality-of-life scores at baseline and after one month were not significantly different in patients in the intervention and control groups.

INTRODUCTION

Premature ejaculation (PE) is the most frequent sexual complaint in men: 21-30% of 18 to 80-year-old men report low or absent control over ejaculation and/or too early ejaculation[1-3]. This is often associated with anorgasmia, low libido, depression, and anxiety that affect the patient and their partners' quality of life[4,5]. The definition of PE by the International Society for Sexual Medicine (ISSM)[6,7] is an "ejaculation that always, or nearly always, occurs prior to, or within about one minute of vaginal penetration; the inability to delay ejaculation during all or most vaginal penetrations, with negative personal consequences, such as distress, anxiety, frustration and/or avoidance of sexual intimacy". Besides the distinction between acquired and lifelong PE, two other categories have been described: "variable PE" and "subjective PE"[8]. Variable PE corresponds to the normal variation in sexual performance. Subjective PE corresponds to a distorted perception of the time before ejaculation: the patient thinks he has PE, although his Intravaginal Ejaculation Latency Time (IELT) is longer than one minute.

General Practitioners (GP) are the first health professionals with whom patients discuss PE[9]. A cross-sectional survey based on structured questionnaires filled in by more than 300 men in German family practices' waiting rooms found that most men considered it important to talk with their GP about their sexual concerns[10]. However, almost half of them wished that their GP would initiate the discussions about sexuality. More than two-thirds of respondents would have liked their GP to signal his/her open-mindedness by directly addressing sexual topics during the consultation[10]. Moreover, 80% of men who participated in the aforementioned study said that they had already experienced, at least occasionally, a sexual problem. However, only 12% of these men consulted their GP about it[10]. The ISSM guidelines emphasise the GP's role in PE management[4]: GPs should "recognise PE and make patients feel comfortable about getting help"[7]. However, GPs often find it difficult to talk about their patients' sexual problems, and do not include sexual history taking in their routine practice[11]. The rate of sexual history taking in primary care is low and depends on the patient's age and GP's training level and gender[12]. Lack of time is the most significant factor[13-17] Moreover, GPs often consider sexual dysfunction

less important compared with delivering information on/detecting sexually transmitted infections and contraceptive counselling[13-17]. They also think that they have insufficient training[10], or are ill-qualified to deal with sexual problems[13, 17-19]. GPs often talk about "Opening a can of worms" when describing their difficulties in addressing sexual dysfunction during consultations[13, 17].

Training in communication skills has been identified as the most important predictor of GPs' willingness to ask patients about their sexual history[20]. In 2009, we carried out a qualitative study to identify strategies used by GPs to initiate discussion on PE[21]. The content analysis of the semi-structured interviews carried out with 11 GPs identified six communication strategies to tackle the subject (described in the Methods section). The present study investigated whether training in communication skills based on these six strategies facilitated discussion of PE between GPs and patients compared with usual care (evaluated as the percentage of patients who mentioned PE with their GP).

METHODS

Study design and participants

The GET UP trial was a randomised, controlled trial with two parallel clusters (intervention group and control group). The study protocol has already been described and is available at the following link[22]. GPs and their patients were from four French regions (Brittany, Aquitaine, Massif Central, and Languedoc-Roussillon-Midi-Pyrénées). They did not receive any payment for their participation. GPs and patients are representative (age, gender, and location distribution) of the French population consulting in primary care[23]. GPs with an exclusive specialty (e.g. acupuncture, homeopathy) or with specialised training in sexology and in communication skills were not included in the study.

The selected GPs consecutively enrolled 18- to 80-year-old men who presented a urogenital, sexual or psychological complaint listed in the International Classification of Primary Care – 2nd edition (ICPC-2). This list was used to guide patient selection. GPs informed the patients about the study after discovering the reason for the visit, at the beginning of the consultation.

Exclusion criteria were patients consulting for other reasons, patients not speaking French, patients with low decision-making capacity (i.e. cognitive impairment, severe depression), and patients unable to sign the written informed consent.

GPs' randomisation was stratified by region and by gender, using block randomisation sequences generated by the Stata software (version 13, StataCorp, College Station, US). The GP's practice was the unit of randomisation. Therefore, all GPs (and their patients) working in the same practice were randomised in the same group (intervention or control) to avoid contamination bias.

GPs in the intervention group and the researchers recruiting the GPs were not blinded to the allocation. However, GPs in the intervention group were asked not to disclose their allocation status to avoid GPs in the control group to become aware of their control status. Patients were blinded to their GP's allocation and the trial primary outcome.

Intervention and control groups

The intervention consisted of an interactive 4-hour workshop to train GPs on the use of the six strategies identified in the qualitative study (intervention group)[22]:

– Being receptive during and particularly at the end of the consultation, just before opening the door, to create a pause that the patients could use to voice their problem.

– Using gentle humour to lighten the atmosphere.

– Matter-of-fact approach (natural and mechanical function of sexuality) to reduce the patient's embarrassment.

– Question on sexual dysfunction during consultations dedicated to sexual health prevention.

–Suggesting some signs and symptoms associated with the current clinical situation (e.g. "you're showing symptoms of depression, and depression can bring physical, psychological and even sexual fatigue") to help the patient to start talking about PE.

– Facilitating the patients' verbal expression; enquiring about their psycho-social and medical history and daily environment enables them to talk about PE.

GPs assigned to the control group provided care according to their usual practice: "clinical care without any value judgment" and centred on the patient[21]. The GPs in the control group attended a 45-minute information session that included a slide presentation to describe the patient inclusion/non-inclusion criteria and the outcome questionnaire. This information session was organised without giving any information on the communication strategies or sexual issues to limit any influence on their usual behaviour[24].

Outcomes

The primary outcome was the percentage of patients who talked about PE with their GP during the inclusion consultation in the intervention and control groups. To determine this percentage, GPs in the two groups were asked to fill in the outcome questionnaire after the consultation. In this questionnaire, they specified whether they discussed about sexual (PE, erectile dysfunction), urinary (dysuria, urinary incontinence), or psychological (anxiety, depression) problems. These different topics were included to avoid contamination bias in the control group. An English version of this questionnaire is available as supplemental material.

Secondary outcomes were i) the percentage of patients with PE, and ii) the patients' quality of life changes between baseline and week 4 post-consultation. PE was evaluated using the validated French version of the Premature Ejaculation Diagnostic Tool (PEDT)[25,26] filled in by the patients at week 4 post-consultation. This 4-week interval between visit and PEDT completion was chosen to dissociate the diagnosis of PE from the consultation and reduce any hypothetical effect of the consultation on the patient's perception of his ejaculation. The PEDT is an extensively validated, self-report measure that uses the Diagnostic and Statistical Manual of Mental Disorders, revised version 4 (DSM-IV-TR) criteria to detect PE[27]. This brief and easy screening tool is recommended by ISSM[8-28]. A score >9 suggests possible PE, and a score ≥11 indicates PE presence.

Quality of life was assessed with the validated French version of the self-report SF-12 questionnaire[29] filled in by patients immediately after the consultation (available in the waiting room) and at week 4 post-consultation (sent back by mail). The 4-week interval was chosen to focus mainly on the PE effects on the quality of life, anticipating that after a longer interval, other problems could also affect the scores.

Statistical methods

Hierarchical regression models (i.e. generalised linear mixed model for the binary endpoint) were used to estimate the intervention effect on the percentage of patients who discussed about PE by taking the inter- and intra-GP variability into account. Intra-class Correlation Coefficients (ICC) were estimated for each group and the results were expressed as absolute differences and 95% confidence intervals (CI). Multivariate analyses were performed to take into account possible confounding factors: sex, age and geographical area for GPs, and age and socioeconomic status for patients. The secondary outcomes were analysed as per-protocol. The SF-12 scores were compared between groups by covariance analysis, with the baseline score as covariate, as suggested by Klar et al[30]. When the SF-12 score at week 4 was missing, it was replaced by the baseline score. Patients with complete data were compared with patients lost to follow-up to validate the sample representativeness.

The PEDT score was analysed as a quantitative variable with the statistical methods used for the SF-12 score, and as a binary outcome (PE/no PE using the score ≥11 and then ≥9 as cut-offs) with a generalised linear mixed model.

A sensitivity analysis was carried out to analyse the attrition bias and to characterise the statistical nature of missing data. There was no significant difference between the profiles of the missing data and analysed data.

Ethical considerations

This study was approved by the Paris Ile de France VII Comité de Protection de la Personne (CPP; n°15-021) for all involved centres (Brittany, Aquitaine, Massif Central, Languedoc-Roussillon-Midi-Pyrénées).

RESULTS

GPs and patients' recruitment

Among the 263 GPs assessed for eligibility in April 2016 and May 2017, 80 were randomised in the intervention (n=42) and control group (n=38) (Figure 1). Twenty-two GPs withdrew during the study period (n=10 in the intervention group, and n=12 in the control group) because they realised that they did not have time for the study. Five additional GPs were recruited and assigned to the control group to have 32 GPs in the intervention group and 31 in the control group. Thirty-two GPs (n=16 in the intervention group and n=16 in the control group) included 130 patients (n=69 in the intervention group and n=61 in the control group).

Baseline characteristics

The baseline characteristics of the GPs in the intervention (n=32) and control groups (n=31) were comparable (Table 1). They were mainly men and working in urban areas. The patients' characteristics (age, living with a partner, social characteristics) in the two groups also were not significantly different (Table 1). Their mean age was 58.5 ± 13.7 years, approximately 75% of them lived with a partner, and one-third were retired.

Primary outcome

The number of patients who talked about PE with their GP during the consultation was significantly higher in the intervention group than in the control group: 29 vs 3 (42% vs. 4.9%, absolute difference = 37%, 95% CI [24% - 50%], p <0.001; ICC = 0.25, 0.41, and 0.24 for the whole sample, the control, and the intervention group, respectively) (Table 2). Similarly, more patients talked about erectile dysfunction in the intervention than in the control group (81.2% vs. 39.3%, absolute difference = 42%, p <0.001) (Table 2).

Secondary outcomes

The SF-12 scores (quality of life) did not significantly change between baseline and week 4 after the consultation in the intervention group (mean difference = -2.9 (-6.1 to 0.4), p=0.08 for physical quality of life; mean difference = 1.9 (-2.1 to 5.5), p=0.35 for mental quality of life), and also between groups (Table 3).

Among the PEDT filled in at week 4, 46 and 34 could be analysed in the intervention and control group, respectively (Figure 2). Using the PEDT cut-off of 11, 37% (n=17) and 20.6% (n=7) of patients in the intervention and control group, respectively, had PE. Using the cut-off of 9, 42.5% of patients had PE (n=23 and n=11 in the intervention and control group, respectively). Moreover, 11 patients with a score ≥9 in the intervention group (48% of 23) talked about PE with their GPs, but none in the control group. In total, 67% of patients with PEDT score ≥11 (n=16/24; n=9 and n=7 in the intervention and control group, respectively) did not talk about PE with their GP.

DISCUSSION

Summary

PE was discussed more often by patients followed by GPs in the intervention than in the control group (42% versus 5% of patients with PE, respectively, p<0.001). This indicates that communication strategies on PE are useful in the naturalistic settings of primary care. GPs can use them to more readily identify patients with PE and offer adapted care.

Concerning the secondary outcomes, the quality-of-life scores at baseline and after one month were not significantly different.

Strengths and limitations

Among the strengths of this study, the cluster design was well suited to the organisation of primary care in France. Moreover, contamination bias was avoided by allocating all GPs from the same practice in the same group. GPs in the control group did not know they were in this group, in order not to affect their behaviour[31]. The ICC was 0.25, meaning that the human

factor role was higher than 20%. The complexity of the GP-patient relationship in primary care consultations, which is the basis of patient-centred care, was respected by the naturalistic context of the study. The six communication strategies were integrated in the French GPs' consultation organisation. The mean length of a GP's consultation is 16.4 minutes in France[32], compared with 11.7 minutes in the United Kingdom[33]. Moreover, French patients pay directly at the consultation end and are then reimbursed by the social security, and choose their practitioner. French GPs generally do the administrative work (e.g. signing prescriptions, sending the information to the social security for reimbursement) during the consultation. Although the French and English healthcare systems are different, the six communicative strategies concern the core of the consultation and therefore, could be easily integrated in any primary care system.

The major limitation was the small number of participating GPs due to the withdrawal of 22 GPs during the study, mainly because of lack of time to devote to the study. Moreover, the 63 GPs participating in the study included only 130 patients, a much lower number than the 600 initially estimated in the sample size calculation. GP recruitment was performed through personal contacts, by targeting friendly networks[34], and by informing and presenting the study using different media. Moreover, several personal emails with positive and encouraging messages were sent to stimulate GPs who had not included any patients yet. Participation in research projects is very uncommon among French GPs[35]. Including patients and filling in questionnaires represent additional and non-routine work. Moreover, French GPs do not like to be observed during their work due to the uncertain and complex world of general practice[35]. These reasons motivated a recruitment through personal contacts to include GPs personally engaged in research. This might be a limitation, but without this strategy we anticipated a lower rate of participation and thus not enough statistical power to detect any effect.

The results are also limited by the small number of patients recruited during the study among whom only 34 patients had a PEDT score ≥9. This small number could also explain the absence of quality-of-life score changes between baseline and week 4. For this study, patients

were not asked to specify their sexual orientation, and this might limit the generalisation of the results. It should be noted that the ISSM definition of PE takes into account only heterosexual and bisexual cis men because it refers only to vaginal penetration[8]. Similarly, no information was collected on the number of partners, sexual intercourse frequency, and history of sexually transmitted infections. Moreover, the GPs did not enquire whether patients talked about these issues with them at their partner(s)' suggestion. This lack of data concerning the patients' sexual history is another study limitation.

Comparison with the existing literature

Many drugs have been studied for PE management[36]. The IELT is the reference to compare the different treatments[37], but it is difficult to use in real practice. Repeated IELT measurements may deter many men from participating in studies, and self-reported measure of ejaculatory latency has greater ecological validity [38]. In naturalistic conditions and in primary care, discussing about the feelings and consequences of PE on the life of the patients and their partners takes precedence over discussion on the IELT. GPs are essential in PE care, but no recommendation is available on how they should proceed to introduce the topic[8,39]. Focusing on IELT and putting the emphasis on this information could reinforce the burden of needing to "last" during sexual intercourse[40, 41]. The focus on the patients and not on their pathology is one of the GPs' core competencies. Therefore, in this study the one-minute criterion or any other time frame was not used to define PE. The patients' distress caused by a real or subjective PE was more important than the theoretical compliance with the PE definition. For the same reason, the self-report PEDT was chosen because it is brief and easy, without time frame.

Finally, these communication strategies are not specific to PE and could be useful for initiating discussion on other sensitive topics. This concrete step of "how to do something in practice and how to be sure that it is efficient" is often lacking in primary care. This study provides concrete communication strategies to initiate discussion in this area.

Implications for research and/or practice

The investigation of an intervention involving six communication strategies and the development of a sexual health communication tool for use in primary care could meet the needs of both practitioners and patients. Implementing these strategies in real practice is the main added value of this study. The ISSM guidelines state that GPs have an important role to play in PE diagnosis and treatment. This study provides a pragmatic way to help GPs to do this.

LIST OF ABBREVIATIONS

CPP: Comité de Protection de la Personne

DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders, revised version 4

GP: General Practitioner

ICC: Intra-class Correlation Coefficient

IELT: Intravaginal Ejaculation Latency Time

ISSM: International Society for Sexual Medicine

PE: Premature Ejaculation

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Ethics approval and consent to participate

The experimental protocol for involving humans included in this study was approved by the Comité de Protection de la Personne CPP de Paris Ile de France VII n°15-021. This central ethics committee approved the study for the various centres (Brittany, Aquitaine, Massif Central, Languedoc-Roussillon-Midi-Pyrénées).

The GPs signed a written consent after receiving information, both by e-mail and by post. The patients received information sheets. The participant GPs discussed the trial with patients in the light of the information provided. The patients signed a written informed consent after information has been delivered orally and in writing, prior to participating in the study and completing the questionnaires.

Competing interests

None declared.

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Consent for publication

Not applicable

Availability of data and materials

All data generated or analysed during this study are included in this published article and its supplementary information files.

Authors' contributions

MB, MC, CM, VR, DC, HVR, SC and BP conceived the study, participated in its design and coordination and helped to draft the manuscript. BP performed the statistical analysis. All authors read and approved the final manuscript.

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Table 1. Characteristics of the GPs and patients involved in the study.

Characteristics	Total	Intervention	Control	P-value
General practitioners*, number	**63**	**32**	**31**	
Age (years), mean ± SD	50.4 ± 10.1	50.4 ± 10.2	50.4 ± 10.0	0.99
Men, number (%)	37 (58.7)	19 (59.4)	18 (58.1)	0.92
Work settings				
Urban vs. Rural, number (%)	38 (60.3)	17 (53.1)	21 (67.7)	0.24
Group practice, number (%)	58 (92)	29 (94)	29 (94)	0.99
General practitioners, number**	**32**	**16**	**16**	
Age (years), mean ± SD	49.1 ± 10.3	46.8 ± 10.4	51.4 ± 10.1	0.22
Men, number (%)	16 (50.0)	7 (43.8)	9 (56.3)	0.48
Work settings				
Urban vs. Rural, number (%)	18 (56.3)	9 (56.3)	9 (56.3)	1.00
Group practice, number (%)	31 (96.9)	15 (93.8)	16 (100.0)	1.00
Patients, number.	**130**	**69**	**61**	
Age (years), mean ± SD	58.5 ± 13.7	56.8 ± 13.7	60.4 ± 13.6	0.13
Living with a partner, number (%)	97/128 (75.8)	53/69 (76.8)	44/59 (74.6)	0.77
Employment status, number (%)				0.75
Working	79 (60.8)	44 (63.7)	35 (57.4)	
No occupation	8 (6.2)	5 (7.3)	3 (4.9)	
Retired	34 (26.1)	16 (23.2)	19 (29.5)	
No information	9 (6.9)	4 (5.8)	5 (8.2)	

**Total number of recruited GPs; **GPs who enrolled patients*

Table 2. Topics discussed during the consultation (outcome questionnaire filled in by GPs)

	Total (n=130)	Intervention (n=69)	Control (n=61)	Absolute difference (95%CI)	P-value (univariate)	P-value (multivariate)
SEXUAL						
Premature ejaculation Number (%)	32 (24.6)	29 (42.0)	3 (4.9)	37% (24% to 50%)	**0.001**	**<0.001**
Erectile dysfunction Number (%)	80 (61.5)	56 (81.2)	24 (39.3)	42% (26% to 57%)	**0.001**	**0.003**
URINARY						
Dysuria Number (%)	87 (66.9)	41 (59.4)	46 (75.4)	-16% (-32% to 0%)	0.055	0.265
Urinary incontinence Number (%)	34 (26.2)	15 (21.7)	19 (31.2)	-9% (-25% to 6%)	0.235	0.686
PSYCHOLOGICAL						
Anxiety Number (%)	76 (58.5)	44 (63.8)	32 (52.5)	11% (-6% to 28%)	0.400	**0.042**
Depression Number (%)	51 (39.2)	29 (42.0)	22 (36.1)	6% (-11% to 23%)	0.518	0.330

Table 3. SF-12 scores at baseline and at month 1 after the consultation in the intervention and control groups.

		Baseline ITT/PP	1 month PP	Mean difference 95% CI	P-value
Physical dimension mean ± SD	Intervention group	47.2 ± 8.7 / 46.4 ± 9.0	46.0 ± 9.3	-0.4 (-2.5 to 1.6)	0.69
	Control group	44.3 ± 8.1 / 44.6 ± 8.3	47.2 ± 9.6	2.6 (0.6 to 4.6)	0.01
	Intervention group vs. Control group			**-2.9 (-6.1 to 0.4)**	**0.08**[1] **0.13**[2]
Mental dimension mean ± SD	Intervention group	44.7 ± 8.2 / 45.1 ± 7.6	45.1 ± 9.0	0.0 (-2.5 to 2.5)	0.98
	Control group	46.8 ± 10.5 / 47.6 ± 9.3	44.8 ± 9.4	-2.7 (-5.6 to 13.0)	0.06
	Intervention group vs. Control group			**1.9 (-2.1 to 5.5)**	**0.35**[1] **0.29**[2]

SD: standard deviation
ITT: intention-to-treat analysis; PP: per-protocol analysis.
[1]: PP.
[2]: ITT using the imputation method, i.e. the baseline score was used to replace the score at week 4 when missing.

Figure 1. Study flowchart.

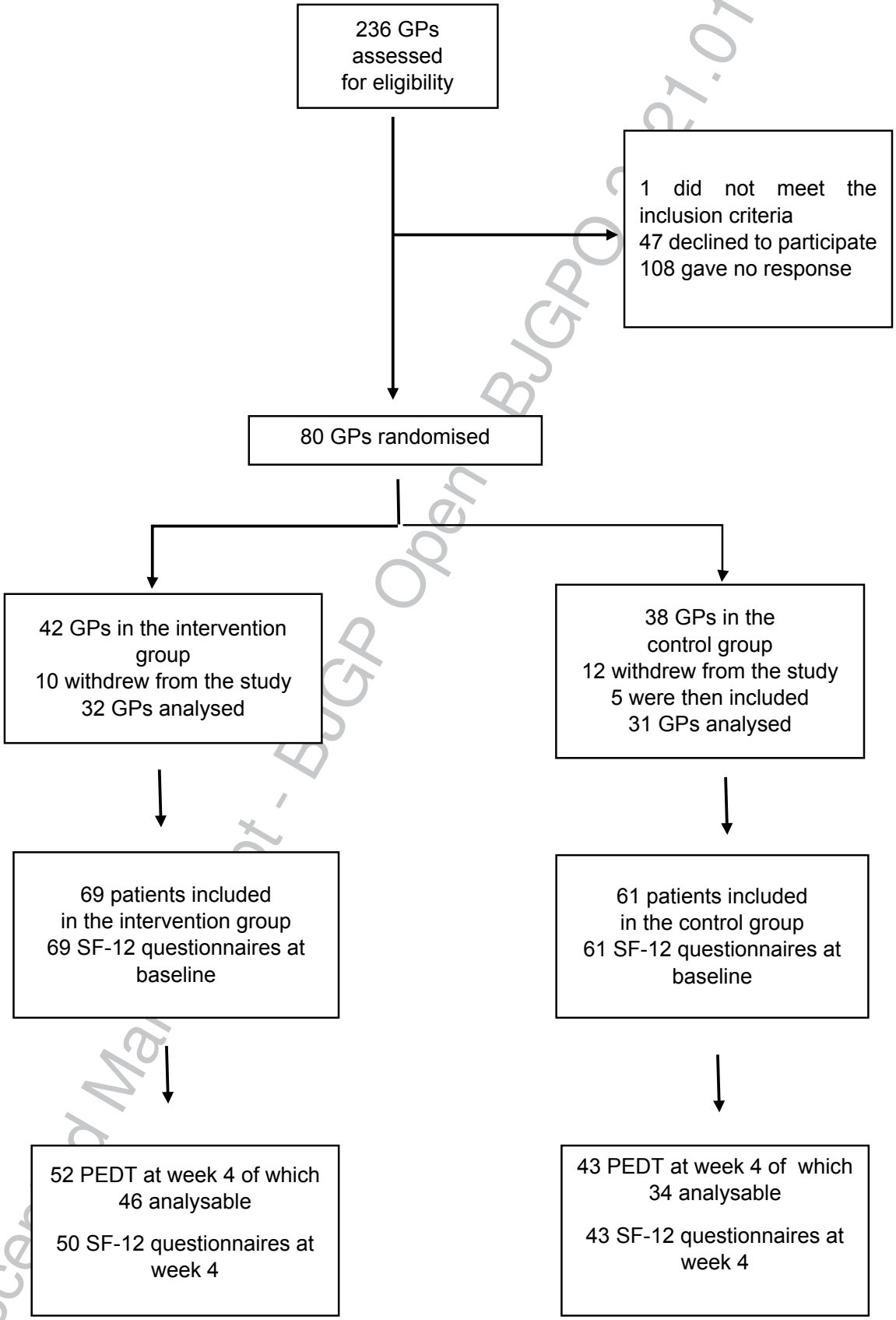

Figure 2. PEDT scores at week 4 after the consultation: ≤8: no PE, 9-10: probable PE, ≥11: PE (p=0.24 between groups).