

## Five-year Outcomes from a Randomised Controlled Trial of a Couples-based Intervention for Men with Localised Prostate Cancer

### Running head: Long term Couple Outcomes after Prostate Cancer

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## Abstract

**Objective:** Psychosexual morbidity is common after prostate cancer treatment; however long-term prospective research is limited. We report five-year outcomes from a couples-based intervention in dyads with men treated for localised prostate cancer with surgery.

**Methods:** A randomised controlled trial was conducted involving 189 heterosexual couples where the man received a radical prostatectomy for prostate cancer. The trial groups were peer support vs. nurse counselling vs. usual care. Primary outcomes were sexual adjustment; unmet sexual supportive care needs; masculine self-esteem; marital satisfaction; utilisation of erectile aids at 2, 3, 4 and 5-year follow-up.

**Results:** The effects of the interventions varied across the primary outcomes. Partners in the peer group had higher sexual adjustment than those in the usual care and nurses group at 2 and 3 years ( $p=0.002$  to  $0.035$ ). Men in usual care had lower unmet sexual supportive care needs than men in the peer and nurse groups ( $p=0.001$ ;  $p=0.01$ ) at 3 years. Women in usual care had lower sexual supportive care needs than women in the peer group at 2 and 3 years ( $p=0.038$ ;  $p=0.001$ ). Men in the peer and nurse group utilised sexual aids more than men in usual care: at 5 years 54% of usual care men vs. 87% of men in peer support and 80% of men in the nurse group.

**Conclusion:** Peer and nurse administered psychosexual interventions have potential for increasing men's adherence to treatments for erectile dysfunction. Optimal effects may be achieved through an integrated approach applying these modes of support.

**Key Words:** Prostate cancer; psychosexual adjustment; couples; partners; peer-support

## Background

Men who undergo radical prostatectomy for prostate cancer typically do not regain preoperative levels of sexual function without treatment[s] <sup>1</sup>. These men report significant unmet physical and psychosexual needs associated with side-effects ranging from reduced penile length to loss of libido, orgasmic dissatisfaction, debilitating sexual and urinary function; altered sexual self-perception and poor intimate relationships <sup>2-5</sup>. In targeting unmet psychosexual burden associated with prostate cancer, the National Institute for Health and Care Excellence (NICE) recommended that men and their partners or carers should be encouraged to discuss psychosexual issues with healthcare professionals <sup>6</sup>. Yet healthcare professionals infrequently address psychosexual concerns among men with prostate cancer <sup>7</sup> and fail to involve their partners in these discussions <sup>8</sup>. Although the psychosocial impact of a prostate cancer diagnosis and treatment on men and their partners is frequently documented <sup>9-12</sup> much less is known about psychosexual needs and effective couples-based interventions.

Moreover, a recent systematic review highlighted a knowledge gap in couples-based interventions, with almost half of the couple interventions producing poor outcomes for partners <sup>13</sup>. For those interventions that were effective, improved relationship and mental health outcomes were reported for the female partner but not the man; by contrast, while sexuality outcomes for the man improved this was not the case for partners. Further, studies only reported short term outcomes, with long-term outcomes (>12 months post diagnosis) not yet reported<sup>13</sup>.

Previously reported twelve month outcomes from a couples-based intervention revealed no differences in psychosexual and relationship outcomes, though couples who received a

peer or nurse led intervention were significantly more likely to use sexual aids compared to couples in usual care<sup>14</sup>. This positive finding is mirrored in a 2006 study<sup>15</sup> and is of clinical significance given the reluctance by many men to use or sustain the use of these aids<sup>16</sup>. The unanswered question therefore was whether this couples-based intervention might lead to longer term improvements in psychosexual outcomes beyond the early assessment period and how long the effect of sexual aids usage might last.

Accordingly, the current study reports long-term five-year psychosexual outcomes from a couples-based intervention targeting men treated for localised prostate cancer with radical prostatectomy.

## **Method**

### *Participants*

These data are from a longitudinal trial of a couples-based intervention. Ethical approval was obtained from the Griffith University Human Research Ethics Committee (PSY/08/08/HREC & PSY/57/13/HREC) and seven public hospitals in Queensland, Australia. The study conformed to the CONSORT statement<sup>17</sup> and the trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12608000358347). Men who were scheduled for or had undergone surgery for prostate cancer within the last 12 months, and their female partners, were recruited between May 2009 and May 2011. A total of 747 patients were referred from 16 urologists in private clinics and public/private hospitals in Queensland, Australia; 35 patients were referred through community awareness of the study. Study inclusion criteria included newly diagnosed with localised prostate cancer and having radical prostatectomy OR less than 12 months post-surgery; in a heterosexual

cohabitating relationship; able to read and speak English; no previous history of head injury, dementia or psychiatric illness; no other concurrent cancer. Of the 782 patients referred to the study, 405 couples met eligibility criteria, and of those, 189 gave their informed consent prior to their inclusion in the study and then completed baseline assessment (46.7%).

Participants completed the couples-based intervention and assessments at 3, 6 and 12 months as part of the trial<sup>14</sup>, and were then approached via letter to participate in an extension of the study involving a series of previously validated self-report measures administered by mail at 2, 3, 4 and 5 years after recruitment. Patients and partners were approached separately for consent to participate in the study extension. Of those patients who consented to the extension, 107 (84%) completed the 5-year assessment; and 91 (80.5%) of consenting partners completed the 5-year assessment (Figure 1). There were no significant differences in age, education level, income level, length of time married and marital satisfaction at baseline between participants who were retained in the study at five years and those who had withdrawn.

### *Intervention*

The two intervention arms of the study have been described in detail previously<sup>14</sup>. In brief, phone support/counselling was telephone-delivered in six (post-surgery recruitment) or eight sessions (pre-surgery recruitment) by nurse counsellors or peer-support volunteers. A cognitive behavioural approach that has been found to be effective in couples-oriented interventions in chronic disease was utilised<sup>18</sup> along with couple relationship education focussed on relationship enhancement and helping the couple to conjointly manage the

stresses of cancer diagnosis and treatment<sup>19</sup>. Both intervention arms included skills training in couple communication and conjoint coping with content and material relevant to the early treatment phase. Written and audio-visual resources were also provided to participants in each intervention arm to supplement the phone contact. Participants in the usual care arm of the study received standard medical management and a set of published patient education materials.

### *Materials*

Primary outcomes were sexual adjustment; unmet sexual supportive care needs; masculine self-esteem; marital satisfaction; utilisation of erectile aids assessed at 2-year, 3 year, 4 year, and 5 year follow-up. Analysis of the data up to 12 months has been reported elsewhere<sup>14</sup>. Here, the analysis is focused on the outcomes from the longer-term assessments at 2 to 5-years after recruitment.

### *Outcome variables*

*Sexual Adjustment.* Men completed the International Index of Erectile Function (IIEF)<sup>20</sup> that assessed their sexual function and satisfaction ( $\alpha= 0.96$  to  $0.98$ ); higher scores indicate better function. Women completed the Female Sexual Function Index (FSFI)<sup>21</sup> which examines sexual function ( $\alpha= 0.92$  to  $0.94$ ); higher scores indicate better function. The Psychological Impact of Erectile Dysfunction – Sexual Experience (PIED-SE)<sup>22</sup> assessed sexual confidence and spontaneity associated with ED ( $\alpha= 0.91$  to  $0.95$ ); higher scores indicate higher sexual confidence associated with ED.

*Sexual Supportive Care Needs.* Couples' needs related to sexual relationships were assessed using the sexuality needs subscale of the Supportive Care Needs Survey<sup>23</sup> ( $\alpha= 0.88$  to 0.98); higher scores reflect greater sexual support needs.

*Masculine Self-Esteem.* The Masculine Self-Esteem scale assessed men's appraisal of their masculinity<sup>24</sup> ( $\alpha= 0.88$  to 0.93), with higher scores indicating greater masculine self-esteem.

*Marital Satisfaction.* The Revised Dyadic Adjustment Scale<sup>25</sup> assessed marital satisfaction via a total score of all items ( $\alpha= 0.76$  to 0.86). Scores equal to or above 48 indicate high marital functioning<sup>26</sup>. The Miller Social Intimacy Scale assessed the current level of intimacy in participants' relationships<sup>27</sup> ( $\alpha= 0.88$  to 0.93); higher scores reflect higher levels of intimacy in the relationship.

*Utilisation of Erectile Dysfunction Treatments.* A scale developed by Schover<sup>28</sup> assessed whether couples have obtained medical help for erectile dysfunction (ED) (e.g., oral medication, penile injections, vacuum devices).

### *Statistical Analyses*

All analyses were run as intention to treat. Categorical variables of the utilisation of sexual aids were assessed using mixed effects logistic regression analyses where the standard care group served as the reference category. For continuous variables, mixed effects regression analyses were conducted. For each type of analysis, time was centred at baseline, and models were run separately for male and female participants. An omnibus model was fit first that included the effects of treatment group and time and follow-up differences were examined using marginal effects at each of the time points.

## Results

The sociodemographic characteristics of participants have been detailed previously<sup>14</sup>. In brief, of the total 189 couples who consented and completed baseline assessment, the mean age was 62.7 years ( $SD=6.8$ ) for men, and 59.8 ( $SD=7.4$ ) for women. Approximately 65.1% of men, and 47.6% of women, had completed tertiary education or technical trade. In terms of employment, 42.3% of men and 25.9% of women were working full-time. Most couples (53.4%) had a household income greater than \$60,000 per year. The mean length of the relationship of the couples was 32.5 years ( $SD=11.8$ ). At the time of baseline assessment, the mean length of time since prostate cancer diagnosis was 127.6 days ( $SD=146.8$ ). All patients in this study underwent radical prostatectomy, with 140 (74%) being recruited prior to surgery, and 49 (26%) being recruited post-surgery. Of those recruited pre-surgery, the men were scheduled to receive treatment in an average of 33.5 days' time post diagnosis ( $SD=32.0$ ). Of those recruited post-surgery, the men were recruited an average of 142.9 days ( $SD=106.8$ ) after treatment.

### *Outcome variables*

Descriptive statistics for the primary outcomes of sexual adjustment, sexuality supportive care needs, masculine self-esteem, marital satisfaction, and utilisation of sexual aids for erectile problems over the assessment periods from baseline to 5-year follow-up are displayed in Table 1 and Table 3 for patients, and in Table 2 for their female partners.

*Sexual Adjustment.* There were no significant group differences for men's self-reported sexual function and satisfaction at the each of the time points post-surgery. At 5 years post-

surgery, men in the usual care group had greater sexual self-confidence than men in the peer group ( $z=-2.02$ ,  $p=0.043$ ).

For women's sexual function, peer group participants had greater function and satisfaction than those in the usual care group at 2 years ( $z=3.17$ ,  $p=0.002$ ) and 3 years ( $z=2.94$ ,  $p=0.003$ ) post-surgery. Further, women in the peer group had greater sexual function and satisfaction than women in the nurse group at 2 years ( $z=-2.27$ ,  $p=0.023$ ) and 3 years post-surgery ( $z=-2.11$ ,  $p=0.035$ ).

*Sexual supportive care needs.* Men in the usual care group had less sexual supportive care needs than men in the peer group ( $z=3.34$ ,  $p=0.001$ ) and the nurse group ( $z=2.59$ ,  $p=0.01$ ) at 3 years post-surgery. Women in the usual care group had less sexual supportive care needs than the women in the peer group at 2 years ( $z=2.07$ ,  $p=0.038$ ) and 3 years ( $z=3.46$ ,  $p=0.001$ ) post-surgery.

*Masculine self-esteem.* Men in the nurse group had greater masculine self-esteem than men in the peer group at 2 years ( $z=1.94$ ,  $p=0.052$ ) and 5 years post-surgery ( $z=2.01$ ,  $p=0.045$ ).

*Marital satisfaction.* At 4 years post-surgery, women in usual care had greater marital satisfaction than women in the peer group ( $z=-2.80$ ,  $p=0.005$ ) and women in the nurse group also had greater marital satisfaction than women in the peer group ( $z=-2.74$ ,  $p=0.006$ ). Women in usual care had greater feelings of intimacy at 2 years ( $z=-2.11$ ,  $p=0.035$ ) and 4 years post-surgery ( $z=-2.48$ ,  $p=0.013$ ) than women in the peer group. Further, women in usual care had greater feelings of intimacy at 2 years ( $z=-2.03$ ,  $p=0.042$ ) and 5 years ( $z=-1.96$ ,  $p=0.050$ ) post-surgery compared to women in the nurse group.

*Utilisation of sexual aids.* As reported previously, there was no significant difference among the study groups in utilisation of medical treatments for erectile dysfunction at baseline<sup>14</sup>. At each annual follow-up period from two to five years, there were significant differences among the study groups for use of medical treatments since surgery (Table 3). Patients in the nurse group utilised tablets more often than the patients in usual care at 2 years ( $z=3.28, p=0.001$ ), 3 years ( $z = 2.04, p = 0.042$ ), 4 years ( $z = 3.30, p = 0.001$ ) and 5 years ( $z = 2.15, p = 0.032$ ), and patients in the peer group used more tablets to treat ED than those in usual care at 4 years ( $z =2.84, p = 0.005$ ) post-surgery. With regards to the use of penile injections, no significant differences were observed between the intervention groups at the 2-5-year time-points. For vacuum devices, insufficient cases were available to provide a reliable analysis and no significant differences were reported.

For overall use of treatments for sexual problems, there were significant differences amongst the intervention groups. Peer group patients used treatments more often than the usual care group at 2 years ( $z = -2.88, p = 0.060$ ), 3 years ( $z = -2.05, p = 0.040$ ), 4 years ( $z = -3.13, p = 0.002$ ), and 5 years ( $z = -2.84, p = 0.005$ ). Nurse group patients used treatment more often than usual care patients at 2 years ( $z = -3.30 p = 0.001$ ), 3 years ( $z = -2.45, p = 0.014$ ), 4 years ( $z = -2.85, p = 0.004$ ), and 5 years ( $z = -2.68, p = 0.007$ ). There were no differences in the use of treatments for erectile dysfunction between the peer and nurse group across the 2 to 5-year period post-surgery.

## **Discussion**

The current study demonstrates that long-term adherence to medical treatments for erectile dysfunction by men with prostate cancer can be greatly enhanced (>80% use) through

nurse or peer couple counselling. This result from a relatively low-intensity telephone delivered intervention is striking, and points to the potential for peer and nurse intervention models to assist heterosexual couples facing the challenges of sexual dysfunction that typically follow radical prostatectomy. In addition, the study protocol demonstrated long-term high adherence to the trial protocol speaking to high acceptability for couple-based intervention approaches in this patient and partner population <sup>29</sup>.

What is more complex, however, is the varying pattern of differences across the two intervention approaches when compared to usual care, and, as in previous research<sup>13</sup> the different effects for men compared to female partners. A recent systematic review of 18 studies reporting coping and adjustment among men with prostate found the following frequently used strategies: (1) avoidance and withdrawal; (2) redirecting cognition and attention; (3) reframing their masculinity and seeking support; (4) retaining pre-illness identity and lifestyle; and (5) symptom/side-effect management. The present study describes contrasting and, in some ways, conflicting and counterintuitive results. Specifically, while couples in the intervention arms had greater utilisation of sexual aids they experienced varied results in terms of sexual support needs, sexual satisfaction, psychosexual interpersonal outcomes. The reasons for this are unclear but may reflect differences in how men and women cope with sexual challenges after prostate cancer both individually and as a couple and the long-term nature of sexual adjustment.

Recovery of erectile function following radical prostatectomy can take up to 4 years to occur, if at all <sup>30</sup>. Over the long term where men may be struggling with both sexual dysfunction and sexual confidence, some couples might come to a state of acceptance of

different, but still satisfying sexual interactions, or a decision to forgo sexual activity, that allows intimacy and sexual self-confidence to rebound<sup>31-33</sup>. This may explain why couples in usual care with less use of sexual aids had lower unmet needs for sexual support, and men had greater sexual self-confidence with partners reporting better marital satisfaction. In addition, disconnections between sexual function and interpersonal variables were evident. For example, partners in the peer intervention had greater sexual function and satisfaction but lower marital satisfaction and intimacy than women in the comparison groups. This requires further gender-based investigation to explore patterns of response in dyads facing prostate cancer.

Differences in responses to the type of intervention (i.e., peer vs. nurse) may not only relate to gender differences, but also mechanism of effect. The two intervention approaches in this study provided similar content but employed different therapeutic mechanisms. Nurse counselling is a professional care approach that is defined by addressing treatment-related physical symptoms, symptom aetiology, symptom prevention and/or treatment and utilization of health care services<sup>34</sup>. By contrast, peer-support is based on personal experience with the specialised knowledge arising from lived experiences and the perspectives that this affords<sup>35</sup>.<sup>36</sup> In this way, peer support provides the patient and the partner with the feeling that they are not alone while also supplying a model for what a recovery of a sexual relationship might look like. Previous research has affirmed the value of peer support to this patient population<sup>37</sup>. Improving long-term psychosexual health may therefore require a framework inclusive of both peer and nurse counselling for couples facing prostate cancer blended to utilise the

strengths of each. Again, more in-depth inductive research is needed to inform a way forward.

#### *Study Limitations*

Strengths of this study include the randomised controlled and prospective trial approach; strong retention of study participants; and unique long-term five-year follow up. Limitations include not including gay or bisexual couples or ethnically diverse participants such that these results may not be generalizable to these population groups. There is a critical need to increase knowledge about the consequences of prostate cancer for these men so as to develop interventions that are appropriate and targeted to their unique needs<sup>38</sup>. In addition, while limiting the inclusion criteria to men treated by surgery is a strength in limiting heterogeneity of side effects, the pattern of adjustment for couples where the man is treated by radiation therapy or androgen blockade will likely differ.

#### *Clinical Implications*

An integrated nurse and peer-support intervention that utilises both modes of support may best advantage men and their partners and prove to be the optimal model of care<sup>39</sup>. This approach would also mirror support successfully used by many prostate cancer support groups who work in concert with local health professionals in a mutually respectful and collaborative care team<sup>40</sup>. However, future research to empirically test an integrated model is warranted.

#### *Conclusion*

In conclusion, the psychosexual burden of a prostate cancer and radical prostatectomy weighs heavily on many couples affecting sexual function, sexual self-confidence, and

marital satisfaction. Peer and nurse interventions in a blended approach have the potential to assist couples following surgery to cope with psychosexual challenges. More research is needed to better understand how sexual function and satisfaction relate to and influence intimacy and marital satisfaction, and how this might differ by gender and diverse established and emergent heterosexual practices.

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#### **Authors' disclosure of potential conflicts of interest**

The author(s) indicate no conflicts of interest.

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Table 1. Descriptive statistics for primary outcome variables for patients by study group (n=number of participants who completed the Self-Administered Questionnaire assessment for each annual time point up to 5 years follow-up).

Variable	2 years			3 years			4 years			5 years		
	Usual Care (n=31)	Peer (n=34)	Nurse (n=28)	Usual Care (n=33)	Peer (n=40)	Nurse	Usual Care (n=30)	Peer (n=38)	Nurse (n=43)	Usual Care (n=28)	Peer (n=38)	Nurse (n=41)
Sexual Function	39.06 (25.93)	34.50 (16.65)	36.13 (21.80)	36.33 (26.23)	32.67 (18.45)	37.44 (22.39)	37.72 (25.59)	30.16 (19.58)	34.26 (23.09)	38.61 (26.49)	27.49 (20.27)	32.49 (21.78)
Sexuality Needs	5.84 (3.77)	6.12 (3.72)	5.70 (3.08)	4.12 (1.88)	6.20 <sup>†</sup> (3.50)	6.02 <sup>‡</sup> (2.93)	4.87 (2.89)	5.32 (2.94)	5.47 (2.71)	4.89 (3.25)	5.71 (3.29)	5.25 (3.06)
Sexual Self Confidence	43.90 (11.26)	42.09 (9.75)	41.73 (10.04)	43.00 (12.66)	40.53 (11.35)	43.10 (10.58)	45.39 (10.70)	40.32 (10.59)	42.56 (11.45)	46.56 (10.07)	38.89 <sup>†</sup> (9.27)	42.45 (11.20)
Masculine Self Esteem	86.67 (14.86)	80.18 (20.93)	84.77 <sup>§</sup> (19.23)	87.50 (20.27)	81.56 (20.40)	86.12 (18.63)	88.33 (11.83)	81.99 (18.37)	86.48 (16.59)	87.95 (14.48)	82.35 (16.74)	87.50 <sup>c</sup> (17.16)
Marital Satisfaction	53.60 (6.34)	52.34 (6.50)	54.10 (7.38)	53.33 (6.40)	52.39 (7.20)	54.44 (6.63)	53.45 (5.43)	53.06 (5.13)	53.95 (6.17)	54.00 (5.82)	53.40 (5.89)	54.10 (6.10)
Intimacy	141.45 (17.26)	138.60 (18.28)	143.36 (16.58)	140.39 (18.62)	139.15 (19.15)	144.14 (20.17)	146.71 (13.79)	140.21 (18.29)	143.16 (15.74)	146.71 (13.79)	141.79 (16.69)	141.68 (17.40)

Note: Higher scores indicate better functioning and quality of life for all primary outcome variables except for sexuality needs

<sup>†</sup> significant difference between usual care and peer groups

<sup>‡</sup> significant difference between usual care and nurse groups

<sup>§</sup> significant difference between peer and nurse groups



Table 2. Descriptive statistics for primary outcome variables for partners by study group (n=number of participants who completed the Self-Administered Questionnaire assessment for each annual time point up to 5 years follow-up).

Variable	2 year			3 year			4 year			5 year		
	Usual Care (n=27)	Peer (n=31)	Nurse (n=35)	Usual Care (n=28)	Peer (n =35)	Nurse (n=38)	Usual Care (n=22)	Peer (n=34)	Nurse (n=37)	Usual Care (n=22)	Peer (n=31)	Nurse (n=37)
Sexual Function	16.49 (5.79)	21.59 <sup>†</sup> (5.69)	18.00 <sup>§</sup> (7.50)	15.81 (5.89)	20.11 <sup>†</sup> (6.88)	17.06 <sup>§</sup> (6.99)	15.41 (6.31)	16.95 (7.62)	17.76 (6.54)	16.91 (5.60)	17.56 (7.30)	16.42 (7.58)
Sexuality Needs	4.67 (2.24)	6.03 <sup>†</sup> (3.19)	5.20 (3.14)	3.67 (2.04)	6.20 <sup>†</sup> (3.33)	5.11 (2.83)	5.14 (3.23)	5.76 (3.66)	4.30 (2.20)	4.14 (2.27)	5.10 (3.03)	4.50 (2.89)
Marital Satisfaction	55.15 (4.87)	51.93 (7.47)	53.12 (6.70)	54.46 (6.89)	53.07 (8.29)	53.58 (6.49)	55.64 (6.64)	50.32 <sup>†</sup> (6.97)	54.53 <sup>§</sup> (6.58)	55.41 (6.20)	52.93 (7.08)	53.42 (6.97)
Intimacy	146.67 (18.07)	140.42 <sup>†</sup> (16.56)	139.06 <sup>‡</sup> (21.41)	145.89 (18.50)	143.41 (17.71)	141.92 (19.13)	147.18 (14.61)	141.65 <sup>†</sup> (15.25)	141.00 (16.66)	148.29 (14.36)	144.80 (17.97)	139.89 <sup>‡</sup> (20.72)

Note: Higher scores indicate better functioning and quality of life for all primary outcome variables except for sexuality needs

<sup>†</sup> significant difference between usual care and peer groups

<sup>‡</sup> significant difference between usual care and nurse groups

<sup>§</sup> significant difference between peer and nurse groups

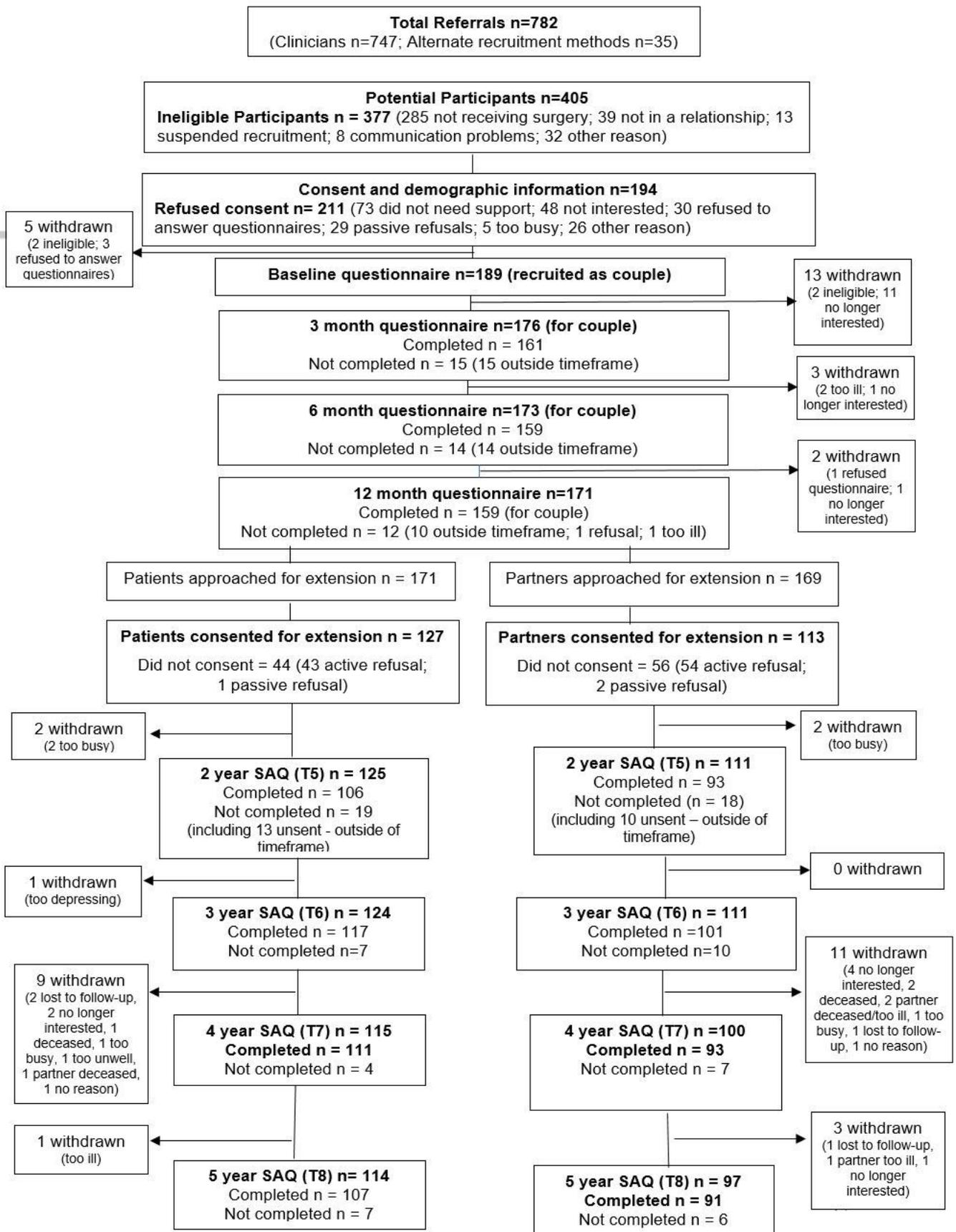
Table 3. Utilisation of medical treatments for erectile dysfunction from 2 years to 5 years follow up.

Medical Treatment	2 years			3 years			4 years			5 years		
	Usual Care % (31)	Peer % (35)	Nurse % (40)	Usual Care % (33)	Peer % (40)	Nurse % (43)	Usual Care % (30)	Peer % (38)	Nurse % (43)	Usual Care % (28)	Peer % (38)	Nurse % (41)
Tablets												
Yes	54.84 (17)	68.57 (24)	85.00 (34) <sup>‡</sup>	45.45 (15)	65.00 (26)	69.77 (30) <sup>‡</sup>	33.33 (10)	71.05 (27) <sup>†</sup>	69.77 (30) <sup>‡</sup>	42.86 (12)	68.42 (26)	65.85 (27) <sup>‡</sup>
No	45.16 (14)	31.43 (11)	15.00 (6)	54.55 (18)	35.00 (14)	30.23 (13)	66.67 (20)	28.95 (11)	30.23 (13)	57.14 (16)	31.58 (12)	34.15 (14)
Injections												
Yes	32.26 (10)	51.43 (18)	42.50 (17)	24.24 (8)	50.00 (20)	39.53 (17)	23.33 (7)	47.37 (18)	41.86 (18)	28.57 (8)	52.63 (20)	36.59 (15)
No	67.74 (21)	48.57 (17)	57.50 (23)	75.76 (25)	50.00 (20)	60.47 (26)	76.67 (23)	52.63 (20)	58.14 (25)	71.43 (20)	47.37 (18)	63.41 (26)
Vacuum												
Yes	3.23 (1)	5.71 (2)	25.00 (10)	6.06 (2)	15.00 (6)	23.26 (10)	3.33 (1)	18.42 (7)	13.95 (6)	7.14 (2)	15.79 (6)	12.20 (5)
No	96.77 (30)	94.29 (33)	75.00 (30)	93.94 (31)	85.00 (34)	76.74 (33)	96.67 (29)	81.58 (31)	86.05 (37)	92.86 (26)	84.21 (32)	87.80 (36)
Overall Use												
Yes	61.29 (19)	88.57 (31) <sup>†</sup>	87.50 (35) <sup>‡</sup>	54.55 (18)	80.00 (32) <sup>†</sup>	81.40 (35) <sup>‡</sup>	46.67 (14)	86.84 (33) <sup>†</sup>	79.07 (34) <sup>‡</sup>	53.57 (15)	86.84 (33) <sup>†</sup>	80.49 (33) <sup>‡</sup>
No	38.71 (12)	11.43 (4)	12.50 (5)	45.45 (15)	20.00 (8)	18.60 (8)	53.33 (16)	13.16 (5)	20.93 (9)	46.43 (13)	13.16 (5)	19.51 (8)

<sup>†</sup> significant difference between usual care and peer groups

<sup>‡</sup> significant difference between usual care and nurse groups

Figure 1. Flowchart of recruitment, participation, data collection and attrition



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