Measuring patient reported outcomes in the POSNOC trial: Strategies employed to promote high quality data return

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1. Introduction

In 2016, a systematic review was published looking at design, implementation and reporting strategies to reduce the instance and impact of missing patient reported outcome (PRO) data[1]. Recommended strategies included: standardised administration procedures for local sites with initial and ongoing PRO training, reminders about upcoming PRO assessments, central monitoring of PRO compliance in real time, active communication and intervention with poorly performing sites. The review emphasised the importance of recording rates and reasons for missing PRO data.

POSNOC is an international multi-centre randomised controlled trial to determine whether axillary clearance / radiotherapy can be avoided safely in women with early breast cancer and one or two involved sentinel nodes who receive standard care with systemic therapy. It is centrally coordinated at Nottingham Clinical Trials Unit (NCTU) with PROs on quality of life (QoL) and long term side effects of axillary treatment managed by Sussex Health Outcomes Research & Education in Cancer (SHORE-C).

The trial opened to recruitment in August 2014 with the strategies listed above already in place.

2. Methods

- PROs are collected from patients entered from the United Kingdom
- QoL and arm morbidity questionnaires: FACT B+4[2], LBCQ[3], QuickDASH[4]
- Anxiety questionnaires: STAI Y1/Y2[5]
- Health economics questionnaire: EQ-5D-5L[6]
- All PROs are completed in clinic at baseline prior to randomisation
- Follow up FACT B+4, EQ-5D-5L, STAI Y1 are posted to patients from SHORE-C
- Follow up LBCQ, QuickDASH are administered by local site staff in clinic or by telephone

Time point	Clinic PROs LBCQ, QuickDASH	Postal (SHORE-C) PROs FACT B+4, STAI Y1, EQ-5D-5L
Baseline	√	√ (+ STAI Y2)
3 months	-	√
6, 12, 24, 36 months	√	√

3. Discontinuation of postal PROs

Patient driven

- Patient withdrawal from trial
- Patient chooses to discontinue questionnaires

Local site / SHORE-C driven

- Local site advises that questionnaires should be discontinued
- PROs not returned at three successive time points

Postal PRO discontinuation time point	Main reasons for discontinuation			
	Withdrawn from trial	Doesn't want to continue with questionnaires	Persistent questionnaire non-return	Other *(died, lost to follow up, change in capacity to complete questionnaires)*
3 months	17	9	-	4
6 months	6	2	-	2
12 months	1	3	5	3
24 months	3	4	12	11
36 months	3	-	6	7
TOTAL	**30**	**18**	**23**	**27**

4. Baseline PRO data collection strategies

Prior to recruitment

- Nottingham CTU site initiation visit in person followed by SHORE-C telephone training
- Staff trained to check questionnaires for missing items with patient present

During recruitment

- Individual site training offered to all new local site staff (NCTU slides, SHORE-C telephone call)
- Liaison with sites to determine most convenient way to supply further baseline questionnaires (hardcopies supplied or site prints them locally)
- Prompt chasing of baseline questionnaire data by NCTU and SHORE-C
- Problems with data addressed promptly with local sites

PRO results to 7th July 2019 (n = 1297 UK patients)

Baseline questionnaire sets not received (n = 26)

	Reason why not received	Number	Percentage return
SHORE-C PROs	Patient withdrew from POSNOC following randomisation	2	
	Patient didn't want to participate in postal PROs	7	
	Questionnaires not given to patient (admin error)	4	
	Patient took questionnaires home and not returned	5	
	Questionnaires completed but mislaid at local site	5	
	TOTAL	**23**	**98.2%**
Clinic PROs	Questionnaires not administered at site (admin error)	26	
	TOTAL	**26**	**97.9%**

5. Follow up PRO data collection strategies

NCTU

- Individual patient PRO data collection schedule available from POSNOC database
- Clinic PRO data collection conducted in clinic or by telephone to fit in with local site pathway
- Prompt query and chasing of clinic PRO data

SHORE-C

- Liaison with local site regarding health status and current contact details prior to posting questionnaires
- Liaison with local site to collect follow up PRO data from patients who require assistance or did not consent for SHORE-C to hold contact details
- Liaison with patient or local site if postal questionnaires not returned

NCTU & SHORE-C

- Reminders and tips regarding PRO data collection addressed in trial newsletters and monthly update memos
- Detailed review of PRO data at each TMG meeting to identify problems and devise solutions (*Example: additional SHORE-C reminder to local sites to collect clinic PRO data introduced in September 2016 following TMG concern over local site compliance)*

Follow up questionnaire sets received

Follow up time point	Clinic PROs	Postal PROs
	No. received / expected (%)	No. received / expected (%)
3 months	-	1065 / 1173 (91%)
6 months (August 2016) ***Prior to introduction of SHORE-C additional reminder***	206 / *251* *(82%)*	-
6 months	986 / 1101 (90%)	1001 / 1082 (93%)
12 months	859 / 950 (90%)	855 / 930 (92%)
24 months	586 / 671 (90%)	560 / 634 (88%)
36 months	304 / 362 (84%)	292 / 328 (89%)

Reasons why questionnaires are not completed at individual time points are collected where possible

6. Conclusion

Our current PRO data indicate that implementation of these strategies together with close collaboration between the whole study team and local sites can achieve high rates of PRO data return and therefore deliver accurate reporting of the effect of the different POSNOC trial treatment allocations on QoL and arm morbidity

[1] Design, implementation and reporting strategies to reduce the instance and impact of missing patient-reported outcome (PRO) data: a systematic review. Mercieca-Bebber R, et al. BMJ Open 2016 Jun 15; 6 (6): e010938. doi:10.1136/bmjopen-2015-010938
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