



Impact on participant recruitment of adding an Infographic to a Patient Information Leaflet in the MABEL trial, a study within a trial (SWAT116)

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Introduction

- Infographics have been shown to improve patient knowledge and understanding of complex information about healthcare such as diagnosis, treatment or discharge planning and aftercare
- They also improve reader experience and user-friendliness.
- Taking these findings into consideration, the implementation of Infographics could help to improve patient experience and understanding of health research.
- A clinical trial Patient Information Sheet (PIS) can be complex and lengthy.
- An infographic containing key information in a more visual and informative way, staying away from large medical terms could be key to improving recruitment.
- This Study Within A Trial (SWAT) was a repetition of SWAT116[1] and looked to investigate whether an Infographic included with the standard PIS would boost/support recruitment.

Methods

- The SWAT was embedded into the Morphine and BrEathLessness Trial (MABEL) (ISRCTN87329095)[2], a multi-centre Clinical Trial of Investigational Medicinal Product (CTIMP) which aimed to recruit 158 participants with chronic breathlessness.
- The SWAT design was a cluster randomised controlled trial comparing the effect of providing potential participants with a Patient and Public Involvement informed Infographic (Figure 1) alongside the PIS with provision of PIS alone on recruitment.
- Sites were randomised in a 1:1 ratio. Sites allocated to the Infographic group were sent the Infographic, to include with the PIS when approaching potential participants
- The primary outcome was the proportion of eligible participants in each group who consented to take part in the host trial after being approached
- This primary outcome was analysed using mixed effect logistic regression with a fixed effect for SWAT allocation and a random intercept for site.

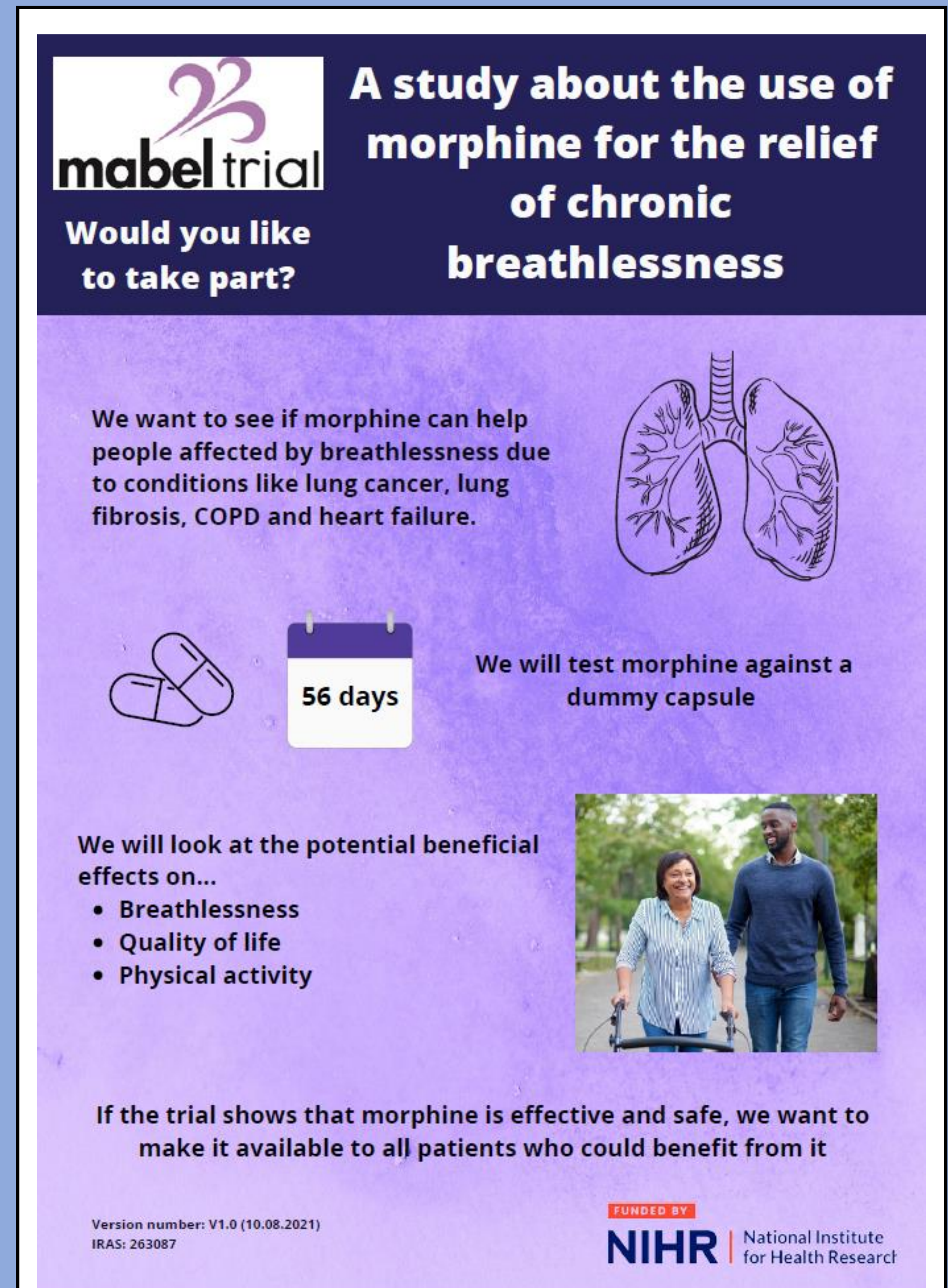


Figure 1. MABEL INFOGRAPHIC

Results

Table 1. Recruitment table

	PIS	PIS + Info	Overall
Number of sites	N=6	N=6	N=12
Eligible patients approached	302	225	527
Consented (%)	56 (18.5 %)	79 (35.1%)	135 (25.6%)

- MABEL opened in March 2021 recruiting 148 participants (94% overall target)
- The SWAT was implemented in November 2021 by which point 13 participants had already been recruited
- Twelve sites were opened to recruitment with 6 sites allocated to infographic and PIS and 6 sites allocated to PIS only
- Although consent rate was 16% higher for those receiving the PIS and Infographic (35.1%) compared PIS alone (18.5%), the difference was not significant (OR 1.91 CI: 0.79 to 4.60; p=0.15)
- The overall cost of printing infographics was £133 for 1500 (9p per infographic) and 8 x postage to sites was £41.49 (~£5.19 each)

Conclusion

- Although results were non-significant, this SWAT demonstrated a positive trend of improvement in recruitment rates when using the PIS and infographic compared to PIS alone suggesting that addition of an infographic to the PIS may potentially support recruitment.
- The cost of implementing the Infographic was relatively low meaning it may be a cost-effective intervention.
- The results can be combined with other studies using SWAT116 in a meta-analysis in the future to improve the statistical power to detect a difference.

References: [1] McCaffery, J; Arundel, C; Chetter, I; Fairhurst, C; Joshi, K; Mott, A; Wilkinson, J. SWAT 116: Impact on recruitment of adding an Infographic to a Patient Information Leaflet <https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/FileStore/Filetoupload,959361,en.pdf> [2] Date K, Williams B, Cohen J, Chaudhuri N, Bajwah S, Pearson M, Higginson I, Norrie J, Keerie C, Tuck S, Hall P, Currow D, Fallon M, Johnson M. Modified-release morphine or placebo for chronic breathlessness: the MABEL trial protocol. ERJ Open Res. 2023 Aug 14;9(4):00167-2023. doi: 10.1183/23120541.00167-2023.

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