

Table 1: Exemplar SWATs evaluating modified PIS designs

SWAT No.	Aim of SWAT	Intervention(s)	Comparison
SWAT 32 ^a Published [13]	To establish if the number of patients recruited and retained in a clinical trial is improved by the use of PIS with different input to their design	<ol style="list-style-type: none"> Enhanced, user tested PIS, plus a user tested covering letter Template PIS developed using an enhanced PIS from another trial in a similar population, plus the original covering letter 	Original PIS, based on the NHS ethics template, plus a covering letter
SWAT 101 ^b Protocol	To explore whether improving the readability of a PIL has an effect on the recruitment rate into an interventional trial	Optimised PIL developed based on similar improved information sheets	Conventional PIL based on Health Research Authority (HRA) example
SWAT 102 ^c Protocol	To determine whether the addition of a pictorial aid to a PIL will improve recruitment in the POSNOC trial	A clearly illustrated pictorial aid at the end of the PIL to depict the randomisation process and crucial information about the two treatment arms in the POSNOC trial	Standard PIL
SWAT 105 ^d Protocol	To compare the effects of a (patient) PPI-designed-and-informed PIS versus a standard, researcher-designed PIS on recruitment to the trial, rate of consent and relationship with participant retention, and understanding regarding the two PIS	PPI-designed-and-informed PIS	Standard researcher designed PIS

^a<https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/FileStore/Filetoupload,679553,en.pdf>

^b<https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/FileStore/Filetoupload,926067,en.pdf>

^c<https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/FileStore/Filetoupload,927252,en.pdf>

^d<https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/FileStore/Filetoupload,926069,en.pdf>

PIL: Participant Information Leaflet; PIS: Participant Information Sheet; POSNOC: POSitive Sentinel NOde; SWAT: Study Within A Trial