SWEET

Participant Flow - BCN Model

TNO		ARM	

Stage	Task	✓
Screening & Approach	*In Person*: Provide PIS at routine appointment/clinic. OR *Remote*: Provide PIS and signed letter of invitation via email/post.	
	Add to screening log.	
Consent	Confirm Eligibility.	
	In Person: complete consent form (3 copies: Original in ISF, Copy in Medical Notes, Copy for Patient). OR *Remote*: complete consent form countersigned by witness (3 copies: Original in ISF, Copy in Medical Notes, Copy for Patient).	
	Provide participant with their copy of the consent form.	
Registration	Complete Registration CRF & Register participant on the database.	
Baseline	Enter the Eligibility CRF on the database.	
	Enter Participant Contact Details CRF on the database.	
	In Person: Patient to complete paper baseline questionnaire at appointment. OR *Remote*: Site send paper baseline questionnaire to participant or if opted for electronic questionnaires this will be automatically released to the participant.	
	If paper baseline questionnaire: return to WCTU using freepost envelope for data entry.	
Randomisation	Randomise participant on database (after you have confirmation of Baseline Questionnaire completion).	
	Send relevant GP letter to the participant's GP.	
	Enter the Baseline CRF on the database.	

Stage	Task	✓
Intervention **Arm A Only**	Once BCN nurse has booked consultation 1: Send initial appointment confirmation letter to the participant.	
	Once BCN nurse has booked consultation 2: Send Follow-up appointment confirmation letter to the participant.	
Follow Up	Enter 6 month follow up CRF on the database.	
	If paper preference indicated: Send out 6 month follow up Questionnaire with free post return envelope.	
	Enter 12 month follow up CRF on the database.	
	If paper preference indicated: Send out 12 month follow up Questionnaire with free post return envelope.	
	Enter 18 month follow up CRF on the database.	
	If paper preference indicated: Send out 18 month follow up Questionnaire with free post return envelope.	
Unscheduled Events	*If participant has an cancer event (e.g. Breast cancer recurrence or New non-breast malignancy)*: complete Event form CRF on database.	
	If participant dies: complete Notification of Death CRF on the database.	
	If participant withdraws: complete Withdrawal CRF on the database.	
	If a Protocol Deviation occurs: complete Protocol Deviation CRF on the database.	

If you have any questions please reach out to us at SWEET@warwick.ac.uk