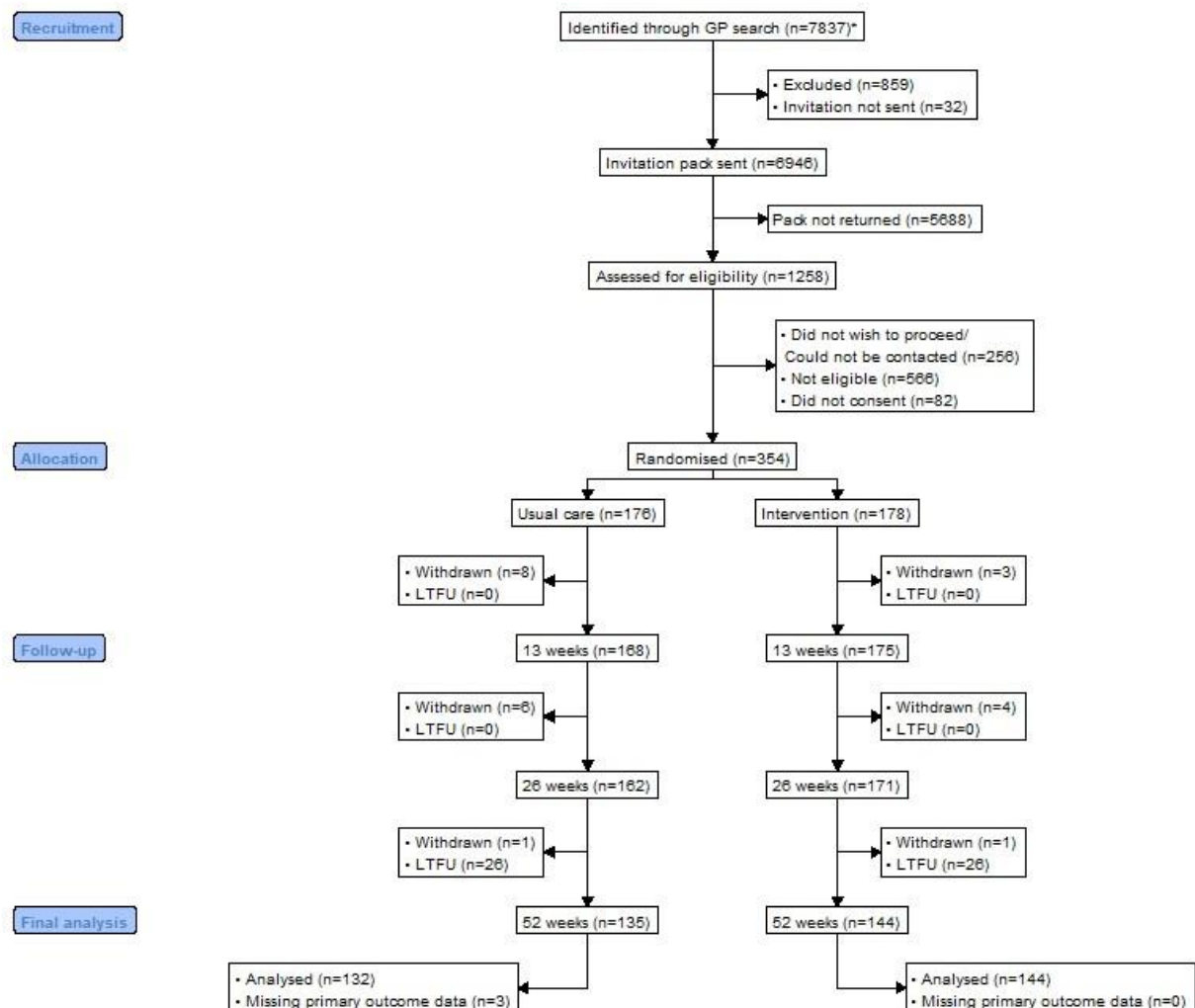# ISRCTN Basic Results Summary for Multiple Symptoms Study 3

Figure 1: Participant flow diagram.

*Missing total number returned by search imputed for four centres using total after exclusions

LTFU = lost to follow-up

Table 1: Participant characteristics at baseline.

	Usual care (N=176)	Intervention (N=178)	Total (N=354)
Age (years)			
Mean (SD)	46.1 (12.9)	45.2 (12.7)	45.6 (12.8)
Median (IQR)	48.0 (36.8, 56.0)	47.0 (35.2, 56.0)	47.0 (36.0, 56.0)
Range	20.0 - 69.0	18.0 - 70.0	18.0 - 70.0
Sex			
Male	32 (18.2%)	31 (17.4%)	63 (17.8%)
Female	144 (81.8%)	147 (82.6%)	291 (82.2%)
Ethnicity			
Asian	7 (4.0%)	7 (3.9%)	14 (4.0%)
Mixed/Other	6 (3.4%)	5 (2.8%)	11 (3.1%)
White	163 (92.6%)	166 (93.3%)	329 (92.9%)
First language			
English language	163 (92.6%)	167 (93.8%)	330 (93.2%)
Other European language	3 (1.7%)	4 (2.2%)	7 (2.0%)
Asian language	5 (2.8%)	1 (0.6%)	6 (1.7%)
Other language	5 (2.8%)	6 (3.4%)	11 (3.1%)
Level of education			
Missing	3	5	8
GSCE or equivalent	61 (35.3%)	59 (34.1%)	120 (34.7%)
A-level or equivalent	48 (27.7%)	43 (24.9%)	91 (26.3%)
Bachelor's degree	40 (23.1%)	49 (28.3%)	89 (25.7%)
Higher degree	15 (8.7%)	15 (8.7%)	30 (8.7%)
No formal qualifications	9 (5.2%)	7 (4.0%)	16 (4.6%)
PHQ-15			
Mean (SD)	14.9 (3.0)	15.0 (2.9)	14.9 (2.9)
Median (IQR)	15.0 (12.9, 17.0)	15.0 (12.2, 17.0)	15.0 (12.9, 17.0)
Range	10.0 - 21.9	10.0 - 23.1	10.0 - 23.1

SD=standard deviation; IQR=Interquartile range; PHQ=patient health questionnaire

Table 2: Estimates of intervention effect at 52 weeks.

PROM	Usual care		Intervention		Adjusted* estimate of effect	Desired effect
	N	Mean (SD)	N	Mean (SD)		
PHQ-15	132	14.1 (3.7)	144	12.2 (4.5)	-1.8 (-2.7, -1.0)	Lower
EQ-5D	128	0.498 (0.298)	130	0.572 (0.267)	0.072 (-0.001, 0.145	Higher
HLS	124	16.2 (4.0)	128	17.1 (3.9)	0.9 (0.1, 1.8)	Higher
ICECAP-A	128	0.721 (0.210)	133	0.756 (0.195)	0.037 (-0.011, 0.085),	Higher
PGIC	124	1.8 (1.2)	130	3.2 (1.9)	1.3 (0.7, 1.9),	Higher
PHQ-9	133	10.9 (6.0)	142	8.8 (6.1)	-1.6 (-5.3, 2.0)	Lower
PROMIS-APS	128	21.1 (8.6)	129	23.7 (9.0)	2.1 (0.0, 4.2),	Higher
SF-6D	117	0.582 (0.109)	127	0.621 (0.139)	0.035 (-0.003, 0.073),	Higher
SF-12 PCS	111	36.1 (11.4)	124	37.1 (11.2)	0.9 (-1.9, 3.7)	Higher
SF-12 MCS	111	38.5 (11.7)	124	42.8 (11.5)	4.6 (1.7, 7.4)	Higher
SSD-12	128	22.9 (11)	133	21.6 (9.9)	-2.2 (-5.3, 1.0)	Lower

PROM=patient reported outcome measure; SD=standard deviation; PHQ=patient health questionnaire; EQ-5D= EuroQol 5 dimension; HLS=health literacy survey; ICECAP-A=ICEpop CAPability measure for Adults; PGIC=patient reported global indicator of change; PROMIS-APS=patient-reported outcomes measurement information system- ability to participate in social roles and activities; SF-6D=short-form six-dimension; SF-12=short form health survery-12; PCS= physical component score; MCS=mental component score; SSD-12=somatic symptom disorder - B criteria scale

*Adjusted for baseline value, age, sex and intervention GP effects

**Unadjusted estimate presented as no baseline PGIC measure

Table 3: Adverse events

Adverse events	Usual care (n=176)		Intervention (n=178)	
	Events	Participants	Events	Participants
Total non-serious events	34	26 (14.8%)	24	21 (11.8%)
- Mental distress[1]	34	26 (14.8%)	22	20 (11.2%)
- Self harm	0	0 (0.0%)	1	1 (0.6%)
- Other	0	0 (0.0%)	1	1 (0.6%)
Total serious events	5	5 (2.8%)	12	9 (5.1%)
- Cancer diagnosis[2]	0	0 (0.0%)	1	1 (0.6%)
- Serious medical condition	0	0 (0.0%)	2	2 (1.1%)
- Suicide attempt	1	1 (0.6%)	0	0 (0.0%)
- Other[3]	4	4 (2.3%)	9	6 (3.4%)

[1] PHQ-9 score of 20 or more and/or a score of 2 or 3 on suicidality item, representing at least a 1 point score change from baseline.

[2] Asymptomatic cancer detected through routine screening programme.

[3] Serious adverse events recorded as 'other' included two overnight hospital stays with unrecorded reasons, two cyst removals, one ectopic pregnancy, one seizure, one patient experiencing chest pain, one with abdominal pain, one depressive episode, one suspected blood clot, one urinary tract infection, one stroke and one suspected stroke.