Obesimed® Forte - Solah VA, Kerr DA, Hunt WJ, Johnson SK, Boushey CJ, Delp EJ, Meng X, Gahler RJ, James AP, Mukhtar AS, Fenton HK, Wood S. Effect of Fibre Supplementation on Body Weight and Composition, Frequency of Eating and Dietary Choice in Overweight Individuals. Nutrients. 2017 Feb 16;9(2).

Authors (year published)	Study design	Total patients	Intervention	Reported outcomes/results	Adverse events	Appraisal	Level
Solah VA 2017	Randomized, three-arm, parallel, blind, placebo-controlled trial	118	PGX (glucomannan + xanthan) 5 g softgel or 5 g granules or 5 g placebo daily	The potential benefits of PGX fibre in controlling frequency of eating and in weight loss	No	D2 A1 P1 R1 T1 O1 F1 S1 C1	I

CASP Questions for making sense of evidence

1. Did the study ask a clearly focused question?	2. Was this a RCT, and was it ap-propriately so?	3. Were participants appropriately allocated to intervention and control groups?	4. Were par-ticipant, staff, and study per-sonnel blinded to participants' study group?	5. Were all participants who entered the trial accounted for at its conclusion?	6. Were the participants in all groups followed up and data collected in the same way?	7. Did the study have enough participants to minimize the play of chance?	8. How are the results presented, and what is the main result?	9. How precise are these results?	10. Were all important outcomes considered so that the results can be applied?
Yes	Yes. Appropriate for this study	Yes. Participants randomly assig-ned to glucoman-nan -xanthan 5 g/d or placebo for 12 weeks.	Yes	Yes. 118 overweight adults	Safety and efficacy data obtained on all patients	Yes-power analysis performed.	PGXG at the recommen-ded dose resulted in a reduction in weight and BMI which was signify-cantly greater than that for RF (p = 0,001).	Statistical tests appro-priately used can have confidence in results.	Efficacy and safety both considered.

<u>Synopsis</u> - Solah VA, Kerr DA, Hunt WJ, Johnson SK, Boushey CJ, Delp EJ, Meng X, Gahler RJ, James AP, Mukhtar AS, Fenton HK, Wood S. Effect of Fibre Supplementation on Body Weight and Composition, Frequency of Eating and Dietary Choice in Overweight Individuals. Nutrients. 2017 Feb 16;9(2).

Aim: determine the effectiveness of fibresupplementation with PolyGlycopleX® (PGX®), on body weight and composition, frequency of eating and dietary intake in overweight adults.
Study design: randomized, three-arm, parallel, blind, placebo-controlled trial.
Subjects: 118 overweight adults aged 25–70 years and with BMI 25–35 kg/m2 were randomised to one of three groups; 4,5 g PGX as softgels (PGXS), 5 g PGX granules (PGXG) or 5 g rice flour (RF) control. PolyGlycopleX (PGX) is a commercial functional fibre complex, manufactured by a proprietary process (EnviroSimplex®) from three dietary fibres: konjac glucomannan, sodium alginate, and xanthan gum. Patients in Arm 1 (PGXS) received 1–2 softgels three times a day in week 1, 2–4 softgels three times a day in week 2 and 4–6 softgels, three times a day in week 3 to week 12. The recommended dose was four (4) to six (6) softgels containing 0,64 g fibre each, three times a day. This represented a supplement of dietary of between 7,6–11,4 g/day. Participants in Arm 2 were instructed to consume 5 g of PGXG containing 4,4 g fibre provided in a single dose foil sachet taken three times a day just before or with meals over the 12-week intervention period. This represented a supplement of dietary fibre of 12,2 g/day. Those in Arm 3 were provided with 5 g of RF containing 4 g fibre in the same dose format as the PGXG, representing 12 g fibre/day. At the end of the 12-week intervention period, measurement of participants' height, weight and waist circumference were repeated.
No adverse events were reported.
Results: in the PGXG group, intention-to-treat analysis showed there was a significant reduction in waist circumference (2,5 cm; $p = 0,003$). Subgroup analysis showed that PGXG supplementation at the recommended dose resulted in a reduction in body weight (-1,4 ± 0,10 kg, $p < 0,01$), body mass index (BMI) reduction (-0,5 ± 0,10, $p < 0,01$), reduced number of eating occasions (-1,4 ± 1,2, $p < 0,01$) and a reduced intake of grain food (-1,52 ± 1,84 serves, $p = 0,019$). PGXG at the recommended dose resulted in a reduction in weight and BMI which was significantly greater than that for RF ($p = 0,001$).
Authors' conclusion: these results demonstrate the potential benefits of PGX fibre in controlling frequency of eating and in weight loss.