

Understanding the public’s views around faecal incontinence and current treatments and the promise offered by new regenerative therapies



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Hypothesis & Aims of Study

Faecal incontinence (FI) is a common condition affecting ~67 million people in Europe to some degree. A proportion have severely impaired quality-of-life, including many women with obstetric anal sphincter injuries.

Such women may benefit from regenerative medicine using autologous skeletal muscle derived cells (ASMDC) to restore function of damaged sphincter muscle. However, progress is hindered by sub-optimal manufacturing and delivery techniques contributing to inconsistent results.

The AMELIE consortium proposes an innovative approach that uses ASMDC attached to implantable microcarriers that will enable delivery of a higher number of viable ASMDC into the damaged sphincter muscle, increasing the likelihood of cell engraftment, regeneration of muscle and improved continence.

As part of the AMELIE programme, we sought to establish whether cultural views about FI vary between European countries and further investigate public perception about regenerative medicine.

Study Design & Methods

As part of the Public and Patient Involvement (PPI) activities, a bespoke AMELIE survey was designed and conducted in conjunction with European national charity collaborators. The survey canvassed public views and awareness about incontinence, current treatments and new regenerative medicine-based therapies. Survey development was led by the UK charity ‘Bowel Research UK’ (BRUK) with input from the World Federation of Incontinence and Pelvic Problems (WFIPP) and the Associació per la Incontinència Anal (ASIA). Translations were provided by AMELIE project partners and ASIA, including Danish, German, French, Italian, Spanish, Portuguese and Dutch. The survey was then embedded into the AMELIE website and officially press-released on the 15th November 2021. BRUK also connected with the charity MASIC who represent AMELIE’s key target group – women with obstetric injuries. MASIC publicized the survey through their network. The survey remained open until the 21st February 2022.

The survey was completed by participants on SurveyMonkey with data collected and imported into Stata 17 MP for analysis. The survey was divided into four sections: ‘about you’, ‘views on and awareness of incontinence’, ‘views on and awareness of current treatments’ and ‘views on the acceptability of new cell therapy treatments for incontinence’.

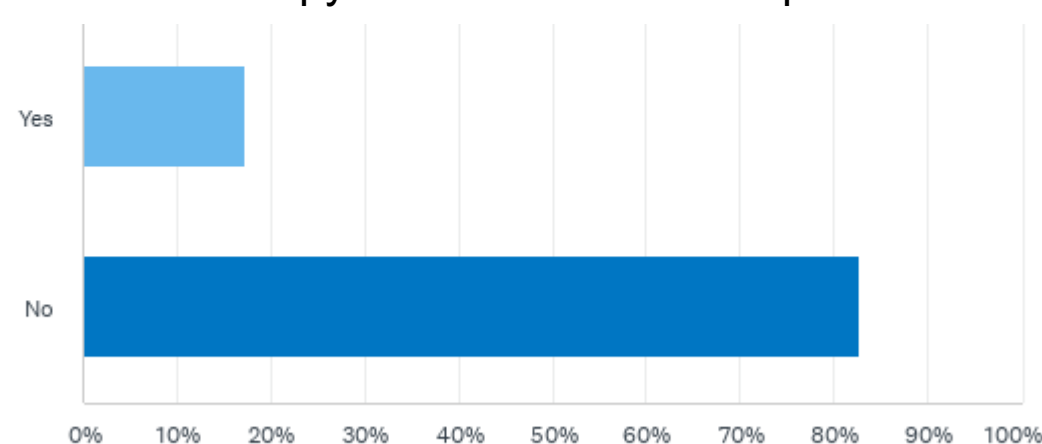
Population group characteristics were analysed using descriptive statistics taken from data collection on the ‘about you’ section. Key demographic categories were divided into Gender (Male or Female), Age (40 years and under, 41-65 years and 66-81 years and over) and Ethnicity (White British, White non-British, Black and/or Asian Ethnic minorities (BAME) and Mixed or multiple ethnic groups). These categories were analysed against each question by section using cross tabulation, reporting counts and using the Chi-squared test, with a 2-sided p-value at a 5% significance level, to identify associations of interest.

Results

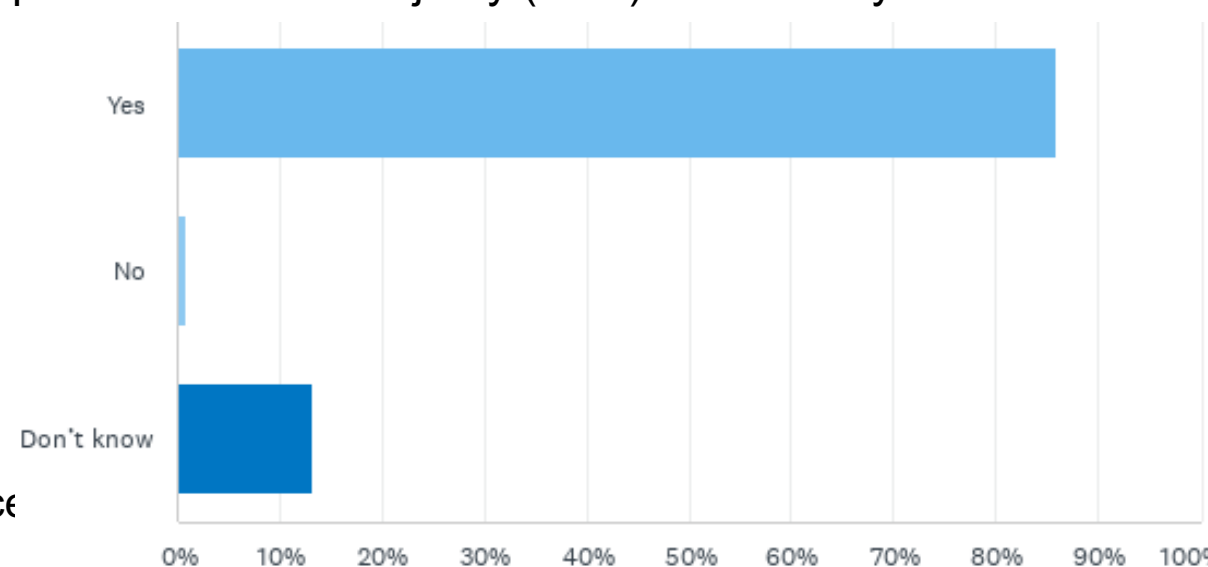
In total, there were **379 respondents** (female: 287 [76%]; majority of females aged 41-65 years [53%]. The highest proportion of respondents were from the UK (229, 60%). Respondents were primarily (80%) White British. Key observations between demographics and views on incontinence showed that females are more likely to answer that **urinary issues are a more serious public health issue than faecal**. Females were more likely to state **that being incontinent is worse than being in moderate pain all the time**. Awareness of health groups/charities was also greater amongst females with 29% fairly or very aware. There were large variations in views by age group, with estimates of the proportion of adults in Europe suffering from FI highest in those aged 41-65 years with 36% of responders estimating it to be 8 – 10%. This age group also consider **being incontinent as being worse than not getting out of bed** (29%). Those aged 66 years and above years believe **incontinence is worse than needing a feeding tube and care all the time** (31% and 26% respectively).

Key findings relating to views and awareness on current treatment include the awareness of pelvic floor (73% vs. 54%) and biofeedback therapy (44% vs. 26%), plus bladder slings/tapes for urinary incontinence (41% vs. 24%) being higher amongst females. Females are also more likely to be aware of digital apps to help monitor and manage incontinence compared to males (20% vs. 12%). Again, we found large variations by age, with those aged 66 years and above much less likely to be aware of most interventions classed as both non-surgical and medical/surgical for both urinary and faecal issues. Additionally, there was lower awareness of any of the treatments highlighted as being available without consulting a doctor in this age group.

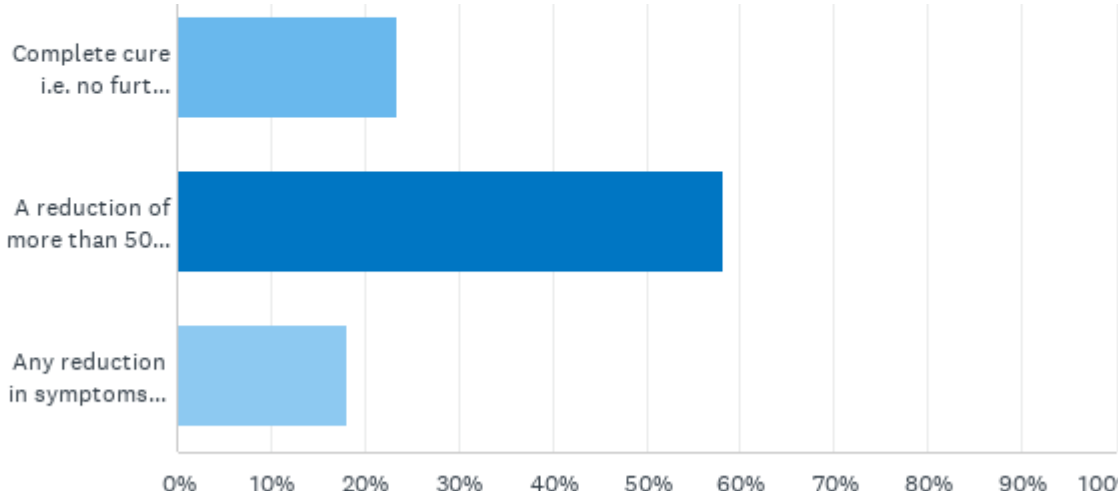
Lastly, views on the acceptability of new regenerative medicine-based cell therapy treatments for incontinence indicate **that younger age groups are more likely to have heard of the terms ‘regenerative medicine’** (57% of 41-65 year olds) and ‘stem cell therapy’ (53% of 41-65 year olds). Non-white British respondents were more likely to have heard of the term ‘tissue engineering’ than White British. We observed some difference between age groups as to whether cell therapy should be trialed for patients with FI, with positive responses from the majority (54%) of 41 – 65 year olds.



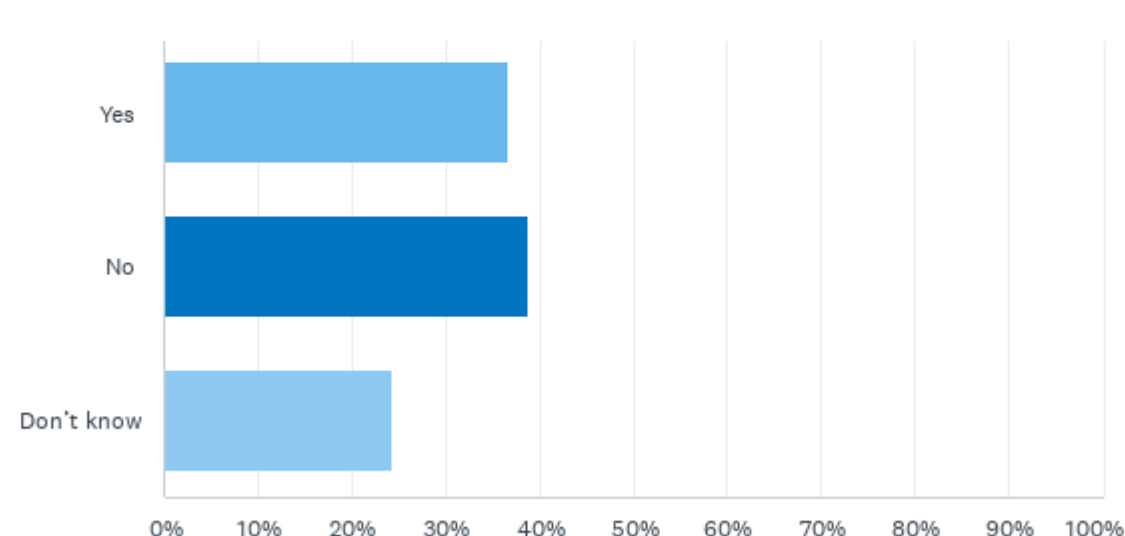
Q35 Have you heard of cell therapy in relation to treatment for incontinence



Q37 Do you think this approach should be trialed for patients with faecal incontinence?



Q41 For a new treatment like AMELIE, who do you consider to be an acceptable treatment response?



Q40 Do you think it is fair to randomise patients to the real treatment and placebo treatment?

Interpretation of Results

Results from the survey confirm that FI is regarded by the public as being a substantial public health problem. Data from the study further highlight the fear people in all age groups have about being incontinent. Whilst there was some awareness of pelvic floor and biofeedback therapy, there was a lack of understanding of other therapies; only a limited number of patient populations were aware of new regenerative medicine technology for this distressing and life-limiting condition.

Conclusion

There is a need for greater public awareness of innovative treatments that are being investigated for treating incontinence. Members of the public are enthusiastic about the possibility of new therapies to restore continence but may need educating about the benefits and risks of unconventional therapies. AMELIE will use this information to generate awareness about FI as a public health issue and to aid trial recruitment.