

Questions to ask about the Intrinsic study

The Intrinsic study has received a lot of coverage in the press recently, but there are questions to ask about the quality and reliability of the research behind the patch.

The Research Process

Normally in research the usual process is to complete a study, submit it for publication in a peer-reviewed, academic journal. Once it's been acknowledged by the scientific community results released to the public via the academic journal, or by the press office of the researcher's university.

In the case of Intrinsic, the study hasn't been published in a peer-reviewed journal. It has been released to the media by a PR company employed by Proctor and Gamble who funded this research. The British Medical Journal has expressed concern that this was a major breach of research protocol and therefore the study couldn't be trusted¹.

(To read their report visit <http://bmj.bmjournals.com/cgi/content/full/329/7477/1255?ehom>).

Transparency

Once research has been made public, it is the duty of the researcher to make the details of their research available. This includes any materials used, full details of how the study was completed, and information about the role of researchers and funding body of the study. Any problems, adverse events, side effects or limitations of the study design should be clearly explained.

In the Intrinsic study the only research information that has been made publicly available is the press release sent out by the PR Company working for Proctor and Gamble. The company has appeared unwilling to provide any further information on the research or measures used in the study¹.

Conflict of Interest

In research, practitioners are expected to declare any conflict of interest they may have. This includes being paid by or having shares in a company who is funding your research. To avoid conflict of interest, researchers should use research tools (e.g. questionnaires) developed by those with no link to the company, or have other objective researchers validate their work to ensure no bias has entered into the study.

In the case of Intrinsic, the researchers were funded by Proctor and Gamble, all the tools (questionnaires) used were created for the purpose of this research by Proctor and Gamble, and several of those involved in the research also have other business links to the company¹. An independent research group has not replicated this research, and until it has, the findings are questionable.

The measures used in the research

There are many measures of female sexual functioning available, created by researchers who weren't funded by companies with a vested interest in the survey's outcome. It is standard practice to find an existing questionnaire, rather than recreating your own². In such cases where questionnaires are to be created for a study they should be carefully validated and tested, and where possible should be designed, assessed and applied by those with no links to the research². The FDA's Guidance for Industry for Female Sexual Dysfunction research specifies that any scales used in research must be fully validated³. As part of good ethical and professional practice, researchers should be willing to promptly pass on any copies of questionnaires or other measures used in their research, to anyone who requests them.

In the Intrinsic study, measures were created in-house and funded by Proctor and Gamble; they were not evaluated by independent researchers. Of the measures (questionnaires) used in this research, the Profile of Female Sexual Functioning has been validated and published. However less is known about the Sexual Activity Log, and literature searches show there are a number of Personal Distress Scale, but it is not clear which one this research used. The researchers, PR Company and Proctor and Gamble have appeared reluctant to pass on any measures used in research.

The Profile of Female Sexual Functioning (PFSF)

Although this research has been published and validated⁴, there are still questions to be asked about the measure itself. The PFSF was developed specifically for research on surgically postmenopausal women. However, it doesn't appear dramatically different from any other measure of female sexual functioning created for non-menopausal women. Certainly there is little focus on questions about being post-menopausal in the PFSF, aside from it being developed from interviews with post-menopausal women. In the validation of this measure, the majority of participants were white women – hardly any Black, Asian, or other ethnic groups were recruited^{4,5}. However the researchers who created the PFSF claim it is an international measure⁴. The questions in the PFSF do measure attitudes to sex, but the causes of these attitudes could be numerous. Typical questions include: "I made up excuses to avoid having sex", or "It was difficult for me to become aroused", or "I was frustrated with my sex life". The causes of these problems could be due to a woman lacking confidence, having a negative attitude towards sex, being in an unhappy relationship, or not knowing or being able to communicate her sexual needs to a partner⁶. These factors are just as likely to be linked to sexual problems⁶, yet the PFSF has been misused as a research tool in the Intrinsa study to suggest that the outcome of sexual problems from the PFSF is simply down to a lack of testosterone.

Ask yourself....

Why hasn't this research been published in an academic, peer-reviewed journal, as is standard practice in medical and health research?

Why has this research only been made available to the public by a PR Company paid for by Proctor and Gamble?

Why do the company and researchers appear reluctant to make their measures and research tools easily available to the public?

Why haven't the researchers invited an independent team to evaluate their study?

Why haven't the researchers used alternative measures (questionnaires) and other materials developed by independent researchers for their research?

Is a study based on mainly White women who are in stable relationships, representative of all post-menopausal women?

How many women refused to participate in the research? Have the researchers told us the answer to this?

Have the researchers made it clear if there were any difficulties in obtaining ethical approval to complete this research – and who granted the ethical approval for the study?

Why have the researchers, the questionnaires used in the study, and the design and reporting of the research itself all been paid for and controlled by Proctor and Gamble?

And finally, question if you can trust....

A piece of research that hasn't been published, that hasn't been approved or welcomed by the wider scientific community, that has prestigious medical journals asking questions about the ethics and robustness of the research, that only focuses on a very narrow area of female sexual functioning, and that presents major conflicts of interest?

References

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