



MACROJOURNALS

# The Journal of **MacroTrends** in Health and Medicine

## **Public Knowledge and Awareness on Safety & Efficacy of Over the Counter Products Labeled by Stem Cell**

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### Abstract

*The Background: Over the counter products labelled with stem cell (OTC-SC), are advertised and promoted in community pharmacies, beauty salons, cosmetic shops and social media. Although the safety and efficacy of OTC-SC products have not been investigated, nevertheless there are increasing demands for, and public acceptability of, these products.*

*Objective: This study was aimed to: i. assess the public awareness and knowledge on efficacy and safety of OTC-SC, ii investigate the success of educational campaign by engaging medical aesthetic clinicians to increase the public knowledge and awareness on OTC-SC.*

*Methodology: A questionnaire was developed and randomly administered to consented participants in Kuala Lumpur. Questions included socio-demographic factors, perception, level of awareness on OTC-SC, and self- knowledge assessment. An educational talk was given by medical aestheticians together with a leaflet. After the educational session, participants answered self-knowledge assessment questions. Total scores of correct answers were used to assess the level of knowledge. Descriptive statistics, one-way ANOVA, and chi-squared test were used for statistical analysis.*

*Results: The response rate was 91%. The majority of participants were 20-29 years old, 80% were female, 78% have a university degree, and the dominant race was Chinese (54%). A total of 92% of the participants were aware of the availability of OTC-SC in Malaysia, however only 24% have consumed these products. The most common concern of consumers was reported to be the nutritional value of OTC-SC. None of the participants were in favor of the idea that the government should ban all of these products in the market, however 54% were in favor of government initiated public education. The educational session significantly increased the score of knowledge from a mean of  $2.18 \pm 1.27$  in the pre-educational test to  $4.32 \pm 1.28$  in the*

*post educational test ( $p=0.00$ ). The leaflet and educational talk conducted by the clinicians were well received by participants.*

*Conclusion: Participants in the selected study sites had poor levels of knowledge regarding stem cell science, even that of educated individuals. The educational campaign by clinicians was able to improve the knowledge and awareness of participants regarding OTC-SC. This kind of educational campaign is cost effective and is generally well accepted by the public.*

Keywords: Educational Campaign; Knowledge, Public Awareness; Stem Cell; Supplement

## 1. Introduction

Healthcare technologies are growing rapidly; consequently new opportunities for research and therapies are available. As a result, information is produced with rapid advances that make it complex for the public to absorb and effectively utilize it in an informed decision process (1). Stem cell research and therapy is considered to be one of the most promising practices in diseases management (2). “Stem cell based products” refers to products that contain or derive from stem cells and are administered to patients (3-4). The “stem cell placenta”, with multiple medical treatment indications as well as the potential capacity of stem cell banking, is one of these stem cell based products. While the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) has yet to formulate any precise guidelines for stem cell based products, both the regulatory frameworks in the EU and USA are structured to assure patient safety. FDA regulations on the human cell, tissue, and cellular and tissue-based products, have provided a regulatory framework for a wide range of stem-cell-based products to ensure the safety and efficacy of these products (5).

Unfortunately, terminologies such as “stem cell based products” and “stem cell placenta” have been widely abused for over the counter products such as supplements and creams due to the rising public demand for these products. Commercial health supplements that are labelled with stem cell based or placenta extract (OTC-SC) have become a new trend in the current dietary supplement menu. There are numerous factors affecting the public’s perception of OTC-SC. Nowadays, advocates for these products are asserting these to be the latest anti-aging health products in the market, thus instantly grabbing public attention. Manufacturers have enhanced the marketing effect by creating the ‘magical’ hype for the fountain of youth. Its effect on younger and youthful celebrities has added points to boost the marketing effects of the products. Since scientific medical terms have generously been used for the labeling statement, the population at-large has more confidence in consuming these anti-aging health products. However, the public in general do not have a medical based background and hence, are not familiar with medical terminologies. Despite the lack of investigation into the safety and efficacy of many of these products, there is an increasing demand and public acceptability for these products. In most instances, consumers are using these products without any consultation with their doctors. The side effects of these products simply remain unreported, underestimated,

and overlooked. In most circumstances, the public has only received a layman's translation from family, friends, relatives, and/or sales promoters.

The public health educational campaign has been playing a significant role in improving public health knowledge. However, to improve health behavior among the public, it is necessary to increase awareness and knowledge about the basic and fundamental science behind health behavior (6). The present study aims to evaluate public knowledge and awareness on the safety and efficacy of OTC-SC and explore any demographic factors associated with the level of knowledge and awareness. Also, medical aesthetic clinicians were engaged in educational sessions to increase public awareness and knowledge on safety perception and behavior upon purchasing supplements labelled by stem cell/placenta. Since clinicians have been reported as the most credible and influential source of health information, this study hypothesized that the educational campaign would be well accepted by the participants.

## **2. Methodology**

### **2.1 Participants**

This cross-sectional study was randomly administered to 100 consented participants in Kuala Lumpur, Malaysia from July 2013 to January 2014. The respondents were recruited from diverse communities including clients of two clinics primarily focused in medical aesthetics, one hospital and a private university campus. Only Malaysians over 18 years old who were able to read, write, and speak in English were eligible to participate in the study. The questionnaires were handed to the recipients by the clinicians and the recipient received a brief explanation regarding the intent and purpose of the research. A research information sheet was provided along with the participant consent form.

### **2.2 Survey Instrument**

The questionnaire was designed by the research team for the present study. A pretest (validation) of the questionnaire was conducted with 10 participants from randomly selected Masters students with a medical and science background to assess the following criteria; time required to complete the questionnaire, the repetition, clarity and relevance of the questions to the research topic, and logical order of the questions. The initial questionnaire included 27 questions, most of which were closed-ended questions with trichotomous choices of yes, no, and not sure. Answers to each question from these 10 participants were reviewed by our team and requisite modifications and deletions were done to validate the questions. Finally, 20 questions out of 27 were included. There were two multichotomic questions with multiple possible answers from a pre-constituted list, giving freedom to the participant to pick one or more of the answers.

The first part of the questionnaire consisted of demographic questions, including age, sex, marital status, race, and level of education. The second part consisted of 6 closed-ended questions and 2 multichotomic questions to evaluate the consumers' awareness, purchasing patterns, and safety perceptions of the OTC-SC. Participant were asked whether they are aware

of OTC-SC product and if yes, have they consumed any of these products. Since brand name sometimes helps consumers remember purchasing history, a list of the most available brands including MFIII placenta extracts soft gel, Zell –V platinum, Cellab Royale Placenta, Kinohimitsu stem cell drink, Health essence sheep placenta, BioDelima stem cell, and Celloceutica sheep placenta, was provided. There was one question regarding factors that influence the participant decision when purchasing the over the counter products including OTC-SC. They were given the choice to choose more than one factor from the pre-constituted list of nutritional value, affordable price, mass media & advertisement effect, pharmacist or clinician recommendation, sales promoter or friend influenced. Part three of the questionnaire included 6 questions to assess the knowledge of participants with regard to OTC-SC. Each participant was requested to answer the same questions before and after the educational session.

### **2.3 Educational Materials and Talk**

Researchers had prepared a three-fold leaflet with two sides (side A & B) as educational materials. In side A of the leaflet, there was a column (fold one) which was entitled “Questions to ask before using the OTC-SC”. In the column two of side A, there were a few recommendations under title of “Doctor’s Advice”. It advised the participants to take the information from their treating doctors and discuss with them what is the most suitable for them. Importantly, it raises concerns about unproven products labelled with stem cell/placenta that are being offered in Malaysia and overseas. They also were informed about availability of the official website National Pharmaceutical Control Bureau ([www.bpfk.gov.my](http://www.bpfk.gov.my)) and US FDA (US Food and Administration (<http://www.fda.gov/forconsumers>) to get more information on OTC-SC. In side B of leaflet, there were some reading materials to help the participants to answer the questions in side A (Table 1), as well as how to identify the products registered with the Drug Control Authority (DCA) in Malaysia. The participants were introduced to two main features; i. Registration number ii. A genuine hologram sticker by providing an image as an example. Moreover, examples of a few certification labels and logos were included.

The educational talk was given along with the pamphlet and commercial pharmacy products booklet. Bottles of multivitamins and anti-oxidants were used as props during the educational session. Verbal instructions were given by clinicians to the participants during the survey questionnaire to avoid any confusion. Also, at the end of the post test, clinician asked if the participant has any question regarding the stem cell placenta product. If there were more than one participant in the educational session then clinicians asked if there was any interest for a group sharing experience and discussion. Although those who were not able to communicate in English language were excluded from the study, during the educational talk the clinicians were willing to communicate in the participant’s preferred language including English, Malay, or Chinese.

The survey and educational campaign lasted for about 30 to 60 minutes depending on the number of participants and their interactions with the survey talk.

## **2.4 Ethical Approval**

Ethical approval was obtained from the research and ethics committee in the Faculty of Medicine and Health Science, UCSI.

## **2.5 Statistical analysis**

The results from each questionnaire were manually entered in the SPSS, version 21. Chi-squared tests were used to test differences in the frequency distribution. Analysis of variance and means were used to determine differences between each group of demographic factors. Scores attributed to OTC-SC knowledge were calculated by summing individuals' correct responses to the questions in part 3 before and after educational intervention. The overall score was the mean of scores that could range from 0 to 6, where a score of 0 means no correct answer and where a score of 6 means that all the answers were correct.  $P < 0.05$  was considered statistically significant.

## **3. Results**

A total of 110 individuals were invited to participate in the study, of which 100 out of these consented to take part in the survey and educational session, and gave response rates of 91%. A summary of the demographic characteristics of respondents is shown in Table 1. The majority of participants, 60 (60%), were 20-29 years old. Overall, 78 (78%) have a university degree. The dominant race was Chinese (54%), followed by Malay (24%). Females accounted for 80% of participants.

Questionnaires in part two comprised of a few issues, which included gauging the level of awareness of OTC-SC products, the purchasing pattern, product safety perception as

Table 1 Characteristics of participants

Characteristic	Number
Age group	
20 and less	10
21-29	60
30-39	24
40-49	2
50-59	4
Gender	
Male	20
Female	80
Race	
Malay	24
Chines	54
Indian	14
Others	8
Educational Level	
Primary	2
Secondray	2
Tertiary	66
MSc/PhD/Other	30

well as the participants' cautionary view. Ninety two percent (n=92) of the participants were aware of the availability of these OTC-SC products in Malaysia. The most common places that have seen by the participants were the well-known franchised pharmacy outlets and the pharmacy section in a shopping complex. Participants recognized certain brands from reading materials as well as from the questionnaire Q7. However, out of the 92 participants, only 24 participants had consumed OTC-SC products, which is 24% of the total participants. Of this 24% (n=24), the majority were from the 20-29 years old age group (n=16) (Table 3), and possessed a tertiary school educational level (n=14). However, this may be due to the fact that the majority of the participants are from this age group are with a tertiary education in the first place.

Unexpectedly, none of the participants in middle and elderly age had consumed the OTC-SC. Also, consuming OTC-SC was prevalent among the participants with higher educational levels since 21% and 27% of those with Tertiary and MSc/PhD, have used the OTC-SC.

With regard to the purchasing pattern of the supplements including stem cell/placenta labelled products, there were a few options of reason given to participants in the questionnaires. According to data collected, the sequence of the factors that influence the participants when

they purchase the OTC-SC include the nutrition value (46%), mass media and advertisement effect (44%), affordable price (38%), pharmacist recommendation (34%), and lastly influence from sales promoters and friends (16%). When they were asked whether there is enough regulatory control for OTC from the Ministry of Health Malaysia, 8.8% said yes, while 29.4% said no and the rest (61.8%) were not sure. Interestingly, none of the participants agreed with the idea that the government should ban all of these products in the market, and only 24% agreed that the government should restrict what is written on labels. Also,, 54% of the participants were in favor of providing government initiated public education for using OTC.

Upon assessing the safety perception, only one third of the participants, consider these OTC health supplements, including stem cell /placenta products to be safe. 28% (n=28) of participants consider it to be unsafe, and 42% (n=42) of the participants are unsure of the products' safety. The majority of the participants fall into the 'Not Sure' status, which is also the most tertiary educational background.

Overall, the educational campaign was able to improve the level of knowledge among participants. Research has come out with the pre and post-test scores based on the number of correct and wrong answers in the test. The answer 'Not sure' was considered as a wrong answer. The minimum total score for pre educational test was 0 while the maximum was 6, with a mean of 2.18 and SD of 1.27. As for the post educational test, the mean was 4.32 and SD was 1.28. On the other hand, the educational session significantly improved the level of knowledge among participants ( $p=0.00$ ) (Table 2). There was no statistically significant association between any of the demographic factors and level of knowledge among participants neither in pre- nor in the post educational test.

Table 2 Pre and Post Health Educational Test

	PRE-TEST		POST-TEST	
	Number of correct answer	Number of wrong answer	Number of correct answer	Number of wrong answer
Q1: Stem cell based products are effective if consumed orally.	22(22%)	78(78%)	86(86%)	14(14%)
Q2: Stem cell based products from plants and animals can be consumed by humans to improve the quality of health.	12(12%)	44(88%)	42(42%)	58(58%)
Q3: The supplement labelled by Stem Cell/ Placenta, always have details of nutrients content.	68(68%)	32 (32%)	76(76%)	24(24%)
Q4: The supplements labelled by Stem Cell /Placenta may contain nutrients which have potential interaction with other medicines or may cause an allergic reaction.	62(62%)	38(38%)	92(92%)	8(8%)
Q5: Plenty of research has been done to evaluate the safety and efficacy of the Stem Cell based Products before they are being sold in the market.	16(16%)	84(84%)	46(46%)	54(54%)
Q6: If a supplement has been sold in the pharmacy, it means it is genuine and effective.	40(40%)	60(60%)	86(86%)	14(14%)

#### 4. Discussion

Stem cell research and therapies are an innovative and novel concept. Debates surrounding this field create conflicts among the general population in many countries (7-8). However, level of knowledge and awareness regarding stem cell therapy varies between different communities according to the amount of public exposure to new medical information via the educational system, social media, TV, and so on. Due to these differences it is necessary to monitor and evaluate the public view, knowledge, and awareness on this contemporary medical application to assure the safety of commercialized related products and services in each country.

The questionnaire survey has been used widely as an instrument to generate data on a range of healthcare related issues from patients' satisfaction to knowledge on contemporary medical technologies and therapies. Additionally, survey questionnaires contained formalized sets of questions which function "to translate the researcher's information needs into a set of specific questions that respondents are willing and able to answer" (9). The significance of the survey data collection to plan public health education needs, design clinical guidelines, and improve

patients' safety, physicians' learning needs and regulatory policy-making has been highlighted in a number of studies (10-14).

Data collected from this survey has been forming a frame with relation to how Malaysian participants perceive the OTC-SC. Almost all were aware of the availability of the supplements mentioned in the survey. The rationale behind this, is that these highly commercialize products are widely available in most of the commonly visited places/outlets by Malaysian consumers. This corresponds with results from Fotee et al. (15), which suggested that awareness with specific dietary nutrients might affect the public's attitude toward the use of dietary supplements. The bonus to these products is their attractive packaging with celebrity advocates and generously advertised promotions in sales outlets. It is expectable that there is a high level of awareness towards the availability of the OTC-SC among Malaysian participants. However, less than one third of participants have actually consumed these products. Our data analysis indicated that the use of OTC-SC is more prevalent among more educated individuals that are either relatively young or middle aged. The same conclusion has been withdrawn from study by Archer et al. (16) in the American population. Moreover, only one third of our participants consider these OTC-SC supplements to be safe. The numbers have actually implied the message that the level of acceptance of participants toward the OTC-SC is relatively low. Health related adverse reactions and side effects have been the majority of concerns. This demonstrates a positive step towards promoting wise supplement consumers in society. In fact, some of these OTC-SC products may have claimed to be the "cure" for certain diseases but may only improve certain health conditions. It is important for consumers to build up their cautionary knowledge on how to choose and consume a safe and suitable supplement that will not jeopardize their health.

This study, as a public health educational campaign, was conducted on a small and inexpensive scale, (outcome and exposure have already occurred) and required less time to be completed. The results from this study correlates with the other studies which found that educational campaigns have a significant impact on public awareness, knowledge, and attitudes on different health concerns (17 – 18). Public education survey campaigns have been having significant impact upon social awareness, knowledge and attitude changes. There is a study conducted by Shim et al. (17) in Korea population regarding the food additives. Questionnaires with pre and post-test were used as assessment tool to gauge the impact of information transmission on consumer knowledge and safety perception, and attitude changes. They also evaluated the overall changes before and after the reading the prepared leaflet and posters. Both knowledge score and safety perception scores signify this improvement. They have successfully implied the health message to the public as well as cultivated positive social attitudes as a food additives consumer. The survey served as a communication tool in our study as well, which allowed us to gather variety of public opinions and comments needed by our researchers. Meanwhile, the public has benefitted from the educational information delivered by the research team. Moreover, using both the educational leaflet and researcher directed talk has reported to increase the success of message delivery during health campaigns (19).

This public educational survey campaign was also initiated to assess purchasing patterns as well as cautionary views regarding the OTC-SC. In addition, the research team in this study had a few other interesting observations. Pre- and post- the educational campaign, we assessed the efficacy of the information delivery as well the participants' responses. Researchers found that middle aged and elderly participants showed more interest upon face-to-face communication, rather than just answering the questionnaire and reading the leaflet alone. Therefore, information delivery through a series of verbal questions and answers was found to be more effective. In terms of the participant perception feedback, researchers have gathered more side information given by the participants through the face-to-face discussion. For example, some participants have shared their supplement purchasing pattern by choosing the well-known direct selling health supplement; some looked for a supplement's expiry date as one of their safety checks when choosing health supplements; some shared their experience of online purchasing of stem cell supplements. There is a study done by Carla and Teri (19), which has also used similar methodology. They have used both of the survey and face-to-face interview methodologies in their knowledge assessment of female supplement users. They indicated that one-on-one interviews are one of the most powerful technique for measuring a person's knowledge. On the other hand, the young participants, mostly students, had different way of providing responses and feedback. For example, the participants who were invited among students in the library of a university campus were more ready to accept the invitation for the health educational survey campaign. They are willing to read the questionnaire and leaflet by themselves first, and showed interest by asking for more information regarding the research topic. The student participants asked more questions from the research team, especially clinicians. They questioned the availability of real stem cell therapy in any clinic/hospital, and asked for clarification regarding the stem cell supplement with the placenta supplement and the efficacy of the current OTC-SC. Overall, the discussion session between the researcher and the students was very interactive. We believe that the differences between our participants in different age groups can be due to the reduced reading habits as a result of 'work' being the dominant life routine in middle aged and the elderly as opposed to the more academic lifestyles of students.

There are numerous health educational survey studies that have been using reading materials to enhance respondent knowledge (17, 20-21). These reading materials are usually in the form of a brochure, pamphlet, posters, etc. For example, a study by Deborah et al (22) has been using consumer guidelines. The FDA Tips for the Savy Supplement User (the revised version) to assess the consumers' intention to use and recommend supplements. Meanwhile, bottles of supplements were used as props throughout the interview by Carla and Teri (19), with the intention to enhance the efficacy as well as the answer quality of the interview session. Researchers have started to use some pharmacy commercial booklets as well as standardized labeled supplement bottles during patient educational survey campaigns. A pharmacy commercial booklet contains a variety of OTC health supplements which including the stem cell/placenta labeled products in pictorial form. With these visual references, respondents have easily recognized the research subjects and were indulged in the educational survey session. Supplement bottles with the standard labeling has been used along with other paper materials

during this survey. Respondents have been given chances to recap on the content delivered by the researcher and revisit guidance provided for choosing supplement products in the market with these educational materials. Most participants showed interest and were fascinated with the researcher's explanation along with the pamphlet, pharmacy commercial booklet, and supplement samples.

The involvement of the researcher with a clinician/doctor status while the survey research was conducted increased the overall efficiency and productivity of the research. In fact, an influential figure that serves as lifesaving medical personnel in society, earns credibility for research from patients as well as the public. Therefore, survey research that involves a member of doctor status is said to be more achievable. The effective engagement of clinicians in health educational campaigns have been reported before (23-24).

Another interesting observation from this study was related to language diversity. The language preference in a multicultural community should be considered during a health educational campaign. The research team has used each participant's preferred language medium (e.g. English, Malay, Mandarin and Cantonese) as a communication tool. The language factor has been directly related to the success of the health educational campaign in the research.

## **5. Conclusion**

Overall the educational survey campaign gained positive feedback from the participants. The present study has been adapted survey approaches in accordance with participants' behavior, leading to the implementation of face to face educational talks, reading out the questionnaire, offering assistance with answering questions, spending more time for the Q&A, supportive reading materials, as well as the use of supplement bottles as props. This campaign has successfully increased participant awareness regarding the significance of the ability to identify the safety and efficacy of supplements bought over the counter, including the highly commercialized OTC-SC. The educational session has displayed the importance of practicing active reading habits as well as the uncovering truth behind a healthy supplement. Our results suggest that special attention should be given to increase level of awareness and healthy behaviors among the younger generation, since they have been found to be the majority of OTC-SC consumers. Our observations from this study clearly indicate that the age of participants and their reading habits should be considered during any health educational campaign. Young participants demonstrated more interest to read the educational materials than the middle aged and elderly participants who were more in favor of educational talks.

The involvement of clinicians in this public health educational campaign is one of the highlight points in this study. Researchers with a medical professional background were found to provide the most reliable health information. Almost all participants have adequately received the health message conveyed via the educational survey regarding the safety and efficacy of OTC-SC. There is high social awareness regarding these highly commercialized OTC products, however the rate of consumption is comparatively low. Researchers have noticed

improvements with participant responses and knowledge of stem cell based products. There was no statistically significant association between any of the demographic factors and educational levels among participants neither in the pre- nor in the post educational test.

Data from this pilot study might be used in the future for multi-centered studies with larger sample sizes and with a longer follow-up duration with the control group for comparison to gauge the social perception and awareness toward the OTC-SC in Malaysia.

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