

EFFECT OF ACUFIRST® BRACELET ON SMOKING GIVING UP

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1 Study Rationale and Experimental Device

Acupuncture, Chinese medical science existing for many centuries, is recognized and well known by the western medical world.

This medicine is based on the evolution of the energy circulating in the human body, conveyed by called ways meridian on the surface of the skin communicating with the internal organs by intermediate ways.

These meridians contain energy points or acupuncture points, the stimulation of which, by needles, by massage or by electric impulsions acts on the behavioural problems of the individual.

These fluctuations in energy represent the evolution of the Yang or the Yin, the Chinese concept of the medicine based on the modifications of these two energies, either in excess, or in deficiency.

There are 14 meridians going through the skin. The channels go from thorax to arms, then from arms to head, then from head to feet, and from feet to thorax following precise schedules according to the solar hour.

The frontside of the wrist is crossed by three meridians, the lung meridian (L), the heart meridian (H) and the master meridian of the heart MH or HS; among these, some points are used to treat specific disorders such as the meridian lung points L7 and L9, the meridian heart points H5, H6, H7 and the master heart meridian points MH6 (HS6), MH7 (HS7).

Heart points H5 (behavioural disorders connected to excesses), H6 + H7 (emotionalism and anxiety) and L7/L9 (respiratory rate and circulatory disorders) are used to treat the stress.

Heart points H5/H6 (rhythm disorders, vago-sympathetic imbalance) and MC7 or HS7 (behavioural disorders, tightness) have effect on the appetite excess

The points H5, MH7 (HS7) and L7/L9 are indicated in the abuse of tobacco consumption.

Their use, the whole set of points or individual point, is known to give noteworthy benefits.

As application of these data, the ACUFIRST® bracelet, using the technique of stimulation of acupuncture points by electric impulses, was conceived to have effect on the behavioural disorders, such as tobacco consumption. Endowed with program called *Anti-Smoking*, the ACUFIRST® bracelet acts through electric impulses of weak voltage and weak intensity stimulating the specific acupuncture points for this program.

The RISE HEALTH and BEAUTY Ltd Company entrusted us with the realization of a study which objective is to demonstrate the effect of the ACUFIRST® bracelet on this disorder of the modern life.

2 Study Design and Investigators

Knowing the effects of stimulating acupuncture points by electric impulses and knowing the configuration of the micro-electrodes of the ACUFIRST® bracelet, we agreed to realize a study on the effect of the bracelet on the smoking giving up.

The ACUFIRST® bracelet has seven versions; within them, the *Anti-Smoking* program.

The location of the bracelet on the right wrist allows the execution of this program.

The bracelet is pre-programmed to shoot an impulse on points having effect on smoking cessation.

The study had lasted two months and had been conducted by 10 therapists, physicians and physiotherapist masseurs, member of the Association for medicine, traumatology and re-education of football for District of Essonne.

Each therapist had to recruit 3 subjects. Finally, 30 subjects had participated in the study and followed the *Anti-Smoking* program.

On Day 0 (D0), the therapist included the subject in the program, after having explained him/her the objectives and schedule of the study, in order to obtain his/her entire cooperation.

Then, the subject was given an ACUFIRST® bracelet and a case report form (CRF).

Every day during 30 days, the subjects were requested to run the bracelet each time he/she wanted to smoke.

The subject reported on the CRF how many times he/she had run the ACUFIRST® bracelet and his/her opinion on its efficacy according to a 4-point scale:

- 0 = not effective,
- 1 = poorly effective,
- 2 = fairly effective
- 3 = very effective.

The subject had to bring the CRF back at the Day 15 (D15) visit (mid-study visit); during this visit the therapist controlled that the subject has used the bracelet as he/she was instructed to, and that the CRF was correctly filled in.

At the final visit Day 30 (D30), the subject brought back the CRF entirely filled in.

The recruitment had appeared to be more difficult than anticipated as a mutual confidence was compulsory to reach the study goals. Anyway, all subjects included in the study had complied with all instructions provided by the therapists:

- they had used the bracelet for the planned 30 days in the *Anti-Smoking* program,
- they all filled in correctly and completely the CRF.

In addition, the subject motivation can be emphasized; it had permitted to collect data of good quality.

The statistical analysis was carried out by Michel Le Faou, MD, supported by a statistician.

3 Subject Characteristics

In the « Anti-Smoking » program, there were 63% men (19 subjects) and 37% women (11 subjects), with a difference of 10 years in the mean age (48 year-old for men and 36.5 year-old for women).

4 Study Results

4.1 Study Data and Statistical Analysis

All 30 subjects filled in and brought back their CRF; so there are no missing data (see section 8: data listings).

We considered as more interesting to analyse the data in term of total number of days of use of ACUFIRST® bracelet for all subjects (i.e. 900 days of use), and to present the distribution of the subject opinion on efficacy during these 900 days.

The day-by-day summary of the subject opinion on efficacy is presented as well; it gives a rough idea on its evolution over time.

4.2 Efficacy on Smoking Giving up

The results show a clear trend in favour of the efficacy on the help to the smoking cessation because during 900 days of use of the ACUFIRST® bracelet, the subjects considered the bracelet as fairly effective during 478 days (53.1%), very effective during 15 days (1.7%) and poorly effective during 371 days (41.2%) (Table 1 and Figure 1).

In summary, the effect of the ACUFIRST® bracelet was noted as effective (fairly or very) during 493 days (54.8%), and poorly or not effective during 407 days (44.2%).

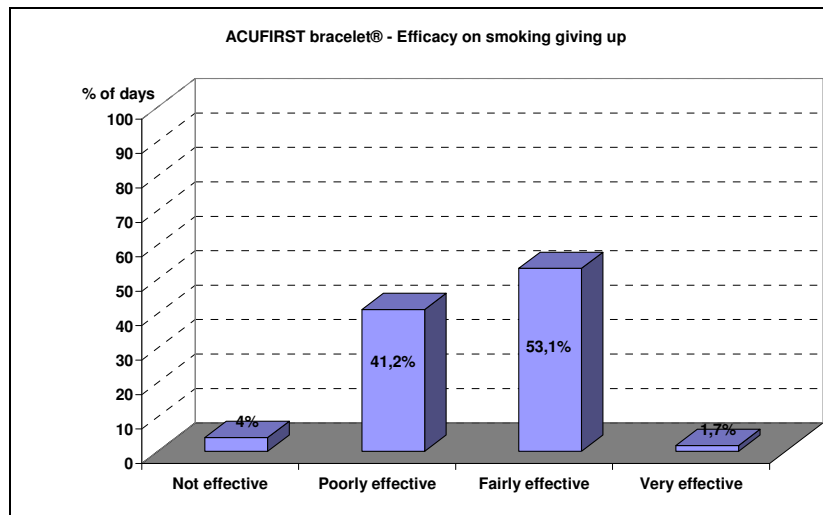
Moreover, three subjects reported having completely given up smoking after the study.(subjects 4, 12 and 18).

Table 1: Subject Opinion on Efficacy of the ACUFIRST® Bracelet on Smoking Giving up

	<i>n</i> *	%
Not effective	36	4.0
Poorly effective	371	41.2
Fairly effective	478	53.1
Very effective	15	1.7
Total	900	100

* *n* total number of days of use

Figure 1: Subject Opinion on Efficacy of the ACUFIRST® Bracelet on Smoking Giving up

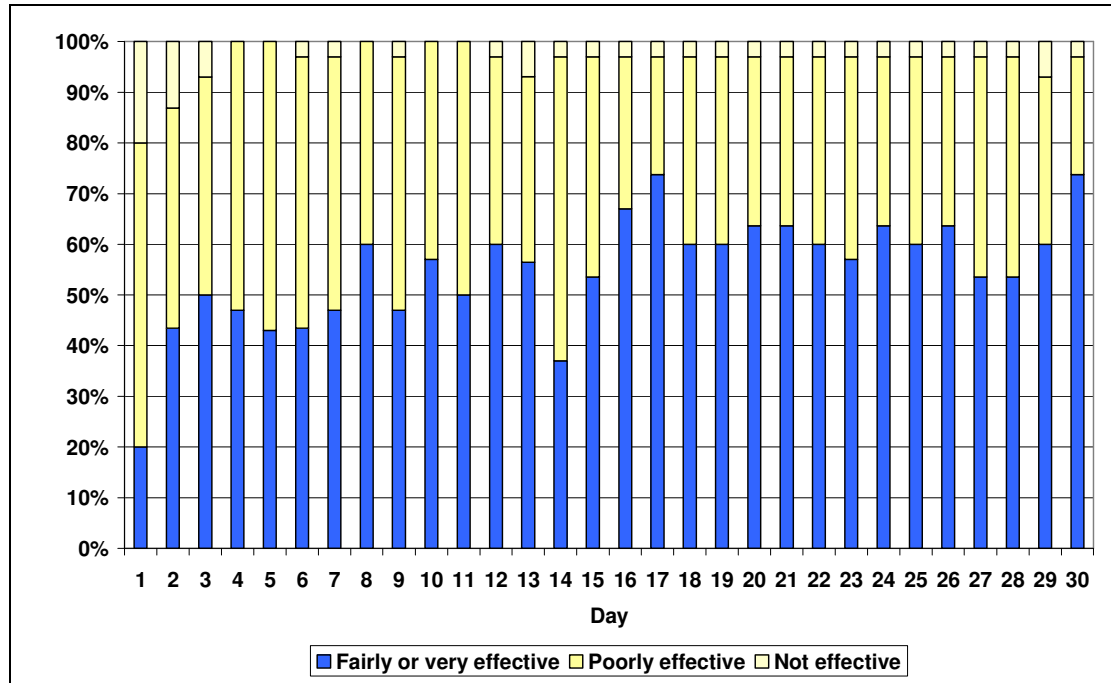


Over time, more half of the subjects judged the bracelet fairly or very effective on the smoking giving up from the 10th day onward, with a peak of 73% on Day 10 and Day 30 (Table 2 and Figure 2).

Table 2: Day-by-day distribution of the: Subject Opinion on Efficacy of the ACUFIRST® Bracelet on Smoking Giving up

<i>Day</i>	<i>Not effective</i>	<i>Poorly effective</i>	<i>Fairly or very effective</i>
<i>01</i>	20%	60%	20%
<i>02</i>	13%	43%	43%
<i>03</i>	7%	43%	50%
<i>04</i>	0%	53%	47%
<i>05</i>	0%	57%	43%
<i>06</i>	3%	53%	43%
<i>07</i>	3%	50%	47%
<i>08</i>	0%	40%	60%
<i>09</i>	3%	50%	47%
<i>10</i>	0%	43%	57%
<i>11</i>	0%	50%	50%
<i>12</i>	3%	37%	60%
<i>13</i>	7%	37%	57%
<i>14</i>	3%	60%	37%
<i>15</i>	3%	43%	53%
<i>16</i>	3%	30%	67%
<i>17</i>	3%	23%	73%
<i>18</i>	3%	37%	60%
<i>19</i>	3%	37%	60%
<i>20</i>	3%	33%	63%
<i>21</i>	3%	33%	63%
<i>22</i>	3%	37%	60%
<i>23</i>	3%	40%	57%
<i>24</i>	3%	33%	63%
<i>25</i>	3%	37%	60%
<i>26</i>	3%	33%	63%
<i>27</i>	3%	43%	53%
<i>28</i>	3%	43%	53%
<i>29</i>	7%	33%	60%
<i>30</i>	3%	23%	73%

Figure 2: Day-by-day distribution of the Subject Opinion on Efficacy of the ACUFIRST® Bracelet on Smoking Giving up



5 Discussion

This open study had evaluated the effect of the bracelet ACUFIRST® on the smoking giving up and had shown a net trend in favour of the efficacy of the bracelet. The statistical analysis of the program data consisted in descriptive presentation of the distribution of the subject opinion on efficacy, expressed in days over the total of 900 days of use, thus 900 opinions of subjects. Moreover, the evolution in time of this opinion was presented by its day-by-day distribution.

However we are aware that the chosen criteria are essentially based on a subjective appreciation by the subject.

It would have been of great interest and more accurate for the smoking giving up program, to consider the actual daily cigarettes consumption, but the record of these data appeared to be difficult.

As a first pragmatic approach, we thus chose to consider the daily opinion of subject during thirty days; the high number of data allows valid statistical calculations.

The manipulation of the ACUFIRST® bracelet was made easier by the pre-programming of the bracelet.

The realization of the study required to target well the subjects and to give them a long and detailed explanation for the understanding of the protocol.

One cutaneous reaction of allergy-type to metal was reported, but in this case the study was completed without worsening.

6 Conclusion

The results obtained in the study reveal a real efficacy of the ACUFIRST® bracelet on the help to the smoking giving up.

The subjects having participated in the study considered that the ACUFIRST® bracelet helped efficiently on the smoking giving up in 55% of cases.

This study relied essentially on subjective criteria and would require to be confirmed by a long-term study, including larger number of subjects.

The technique gives the advantage to make the subject sensitive and responsible of him/herself.

Switching on the bracelet each time a sudden urge to light a cigarette, implies to bring the subject out of its routine and to make him/her become aware of the perverse effect of his/her ritual gesture.

At least for that, the bracelet brings one more weapon in the fight against this disorder of the modern life.

7 Bibliography

André LEBARBIER, Acupuncture pratique, ed. Maisonneuve, 1975

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8 Efficacy Data Listings

Listing 1 : Individual Efficacy Data on the Smoking Giving up

SUBJECT INITIALS																														
Day	P.T.	M.B.	M.L.	B.C.	G.M.	M.P.	J.S.	T.D.	B.G.	M.P.	A.A.	M.L.	N.B.	A.N.	D.A.	A.S.	D.M.	E.F.	S.S.	M.M.	J.R.	B.S.	O.S.	G.M.	D.B.	M.K.	C.C.	J.K.	P.M.	F.S.
01	1	2	0	1	2	1	1	1	1	1	2	0	1	2	0	1	1	1	1	0	1	1	2	1	1	0	1	0	1	2
02	1	2	0	2	2	1	1	2	2	2	2	1	1	3	1	1	2	1	1	0	1	2	2	2	1	0	1	0	1	2
03	2	2	1	2	2	2	1	2	1	2	2	1	2	3	1	1	2	1	1	1	1	2	2	2	2	0	1	0	1	1
04	2	2	1	2	2	2	1	1	2	2	2	2	1	2	1	1	2	2	1	1	1	1	1	1	2	1	1	1	2	1
05	2	2	1	2	2	1	1	1	2	2	2	2	2	1	1	1	1	2	1	1	1	1	1	1	2	1	2	1	2	1
06	2	2	1	2	2	1	1	2	1	1	1	2	2	1	0	1	1	1	1	1	1	2	2	1	2	1	2	1	2	2
07	1	2	1	2	1	2	1	2	1	1	1	1	2	0	2	1	2	1	1	1	2	2	2	2	2	1	1	1	2	2
08	2	2	1	2	2	2	1	2	1	1	2	2	2	1	2	1	2	1	1	2	2	2	2	2	1	1	1	1	2	2
09	2	2	1	2	2	1	1	1	1	2	2	2	1	2	2	1	0	2	1	2	2	1	1	2	1	1	1	1	1	2
10	2	2	1	2	2	2	1	2	2	2	2	2	1	2	2	1	1	2	1	1	1	2	2	2	2	1	1	1	1	1
11	2	2	1	2	2	2	1	2	2	2	2	1	1	1	1	1	1	2	1	2	1	2	1	2	2	1	1	1	1	1
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17	2	2	0	2	2	2	1	2	2	2	2	3	2	1	2	2	1	3	1	2	1	3	2	2	2	2	2	1	2	1
18	2	2	0	2	2	2	1	2	2	2	2	3	2	1	1	1	1	3	1	1	1	3	1	2	2	2	2	1	2	1
19	2	1	0	2	2	1	1	1	2	2	2	3	3	2	2	1	2	2	1	1	1	2	1	2	2	2	2	1	3	1
20	2	1	0	2	2	2	1	1	2	2	2	2	2	1	2	1	2	2	1	1	2	2	2	1	2	1	2	1	2	2
21	1	2	0	2	2	2	1	1	1	2	2	2	2	2	2	1	2	2	1	1	2	3	2	2	1	1	2	1	2	2
22	1	2	0	2	2	2	1	2	2	1	1	2	1	1	2	1	2	2	1	2	2	2	2	2	1	1	2	1	2	2
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24	2	2	0	2	2	2	1	1	1	2	1	3	2	2	2	1	2	2	1	1	1	2	2	1	2	2	2	1	2	2

SUBJECT INITIALS																														
Day	P.T.	M.B.	M.L.	B.C.	G.M.	M.P.	J.S.	T.D.	B.G.	M.P.	A.A.	M.L.	N.B.	A.N.	D.A.	A.S.	D.M.	E.F.	S.S.	M.M.	J.R.	B.S.	O.S.	G.M.	D.B.	M.K.	C.C.	J.K.	P.M.	F.S.
25	2	2	0	2	1	1	1	1	2	2	2	2	1	1	2	1	2	2	1	2	1	2	2	1	2	2	2	1	2	2
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