

EFFECT OF ACUFIRST® BRACELET ON INSOMNIA

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

Heart points H5/H6 (rhythm disorder, vago-sympathetic imbalance) and MC7 or HS7 (behavioural disorder, 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 disorder, such as Insomnia. Endowed with program called *Insomnia*, 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.

The study duration was two months.

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 insomnia.

The ACUFIRST® bracelet has seven versions; within them *Insomnia* 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 Insomnia.

The study had lasted two months and had been conducted by 8 investigators, 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, 27 subjects had participated in the study and followed the *Insomnia* program, leading to a total 810 days of use.

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 for him/her to give his/her entire cooperation.

Each subject had to attend three visits to be followed by the therapist: on Day 0 (inclusion day), on Day 15 (mid-study visit) and on Day 30 (final visit).

1. On Day 0, the therapist included the subject in the *Insomnia* 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 had difficulty to fall asleep.

Every day, the subject reported on the CRF his/her opinion on its efficacy according to a 4-point scale:

- 0 = not effective,
 - 1 = poorly effective,
 - 2 = fairly effective
 - 3 = very effective.
2. On Day 15 (mid-study visit), the subject had to bring back the CRF ; 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.
 3. On Day 30 (final visit), at the final visit Day 30 (D30), the subject brought back the CRF entirely filled in.

The study consisted in bringing to light the effect of the bracelet on this unpleasant and frequent state of the everyday life that is the insomnia.

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

3 Subject Characteristics

The subjects in the “Insomnia” program were rather women (15, i.e. 56% vs. 12 men, i.e. 44%) almost ten years older than the men (59.5 year-old for the women vs. 50.5 year-old for the men).

The recruitment had appeared to be more difficult than anticipated as a mutual confidence was compulsory to reach the study goals. Anyway, the subjects’ motivation can be emphasized; they have globally respected the therapist’s instructions.

4 Effect on Insomnia

The results show a clear trend in favour of the efficacy on the insomnia. During the 810 days of use of the ACUFIRST® bracelet, the subjects considered the bracelet as fairly effective during 424 days (52.3%), very effective during 93 days (11.5%) and poorly effective during 241 days (29.8%).

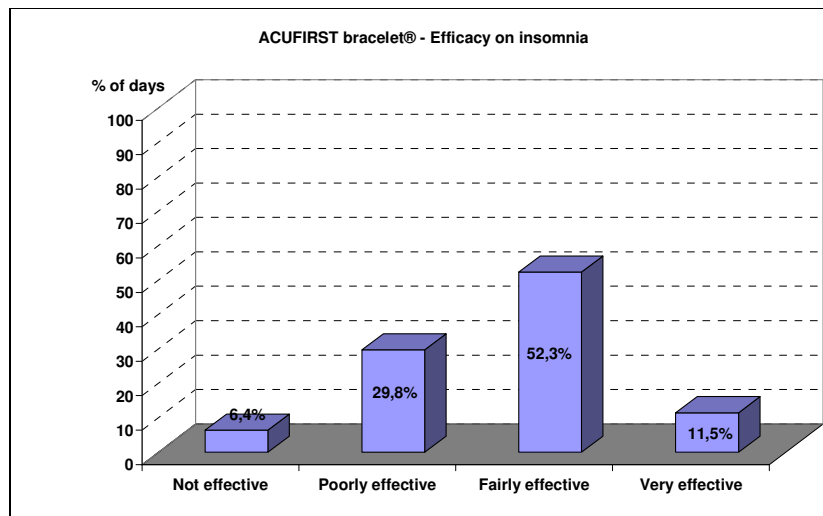
In summary, the effect of the ACUFIRST® bracelet was noted as effective (fairly or very) during 517 days (63.8%), and poorly or not effective during 293 days (36.2%).

Table 1 : Efficacy on Insomnia

	<i>n</i> *	%
Not effective	52	6.4
Poorly effective	241	29.8
Fairly effective	424	52.3
Very effective	93	11.5
Total	810	100.0

* *n* total number of days of use

Figure 1 : Efficacy on Insomnia



5 DISCUSSION

This open study had evaluated the effect of the ACUFIRST® bracelet on the Insomnia and had shown a net trend in favour of the efficacy of the bracelet without any cutaneous adverse event (such as allergy to metal).

However we are aware that the statistical analyses are based essentially on a subjective appreciation by the subject.

We would have been able to assess more “clinical” parameters such as detailed sleep disorders in the *Insomnia* program. But it would have required too important logistics.

Anyway, the number of data is sufficiently high and allows acceptable statistical calculations.

Moreover, the ACUFIRST® bracelet is easy to use and aims at any patient type presenting this trouble of the modern life.

It constitutes a non aggressive therapy, which, beyond the benefits of the acupuncture, induces the subject to take care of him/her self.

6 CONCLUSION

The results obtained in the study reveal a real efficacy of the ACUFIRST® bracelet on the Insomnia (517 days on the 810 days of use, i.e. 63.8%).

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

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

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

J.A. LAVIER, *Vademecum d’acupuncture symptomatique* ed. Maloine, 1985

8 Efficacy Data Listing

Listing 1 : Individual Efficacy Data on Insomnia

SUBJECT INITIALS																											
Day	HR	GL	RV	MB	JCD	CM	DS	MJP	MP	TB	ND	DD	CC	BT	CZ	SL	JB	GM	MMD	CG	AR	JJ	JF	CL	FV	MG	BD
01	3	1	0	0	0	0	2	2	2	1	2	0	0	2	2	1	1	3	1	3	0	2	1	2	1	2	2
02	2	0	1	0	0	0	3	3	1	1	2	1	1	1	2	2	1	2	1	3	1	2	1	2	2	2	2
03	3	1	1	0	0	1	1	2	2	1	2	1	2	1	2	2	1	2	2	2	1	2	1	1	2	1	2
04	3	1	2	0	1	0	3	1	2	1	1	1	3	1	2	2	1	1	2	2	1	2	1	1	2	1	2
05	3	0	1	0	1	1	3	3	2	1	1	1	3	1	2	2	2	1	1	2	2	2	1	2	1	1	2
06	2	0	1	1	1	1	2	2	3	1	2	1	3	1	2	2	2	1	2	2	1	1	1	2	1	1	2
07	3	1	2	1	1	0	2	0	3	1	2	0	3	2	1	1	2	1	2	1	1	2	1	2	2	1	2
08	3	1	2	1	1	1	1	1	2	1	0	1	3	2	1	1	2	1	2	1	2	2	1	1	2	1	1
09	3	0	2	1	1	2	3	2	2	1	2	1	3	2	2	2	3	2	2	1	2	2	1	1	2	1	1
10	3	0	0	1	1	0	2	3	2	1	2	1	3	1	2	3	3	2	2	1	1	2	1	1	2	2	2
11	3	1	1	1	2	0	2	2	2	1	2	1	3	2	2	2	1	2	1	2	2	3	1	2	1	2	2
12	3	0	1	2	1	1	3	2	2	1	2	1	3	2	3	2	2	2	0	2	2	3	1	2	2	2	2
13	3	1	2	2	2	1	2	2	1	1	2	1	3	2	2	2	2	1	0	2	2	2	1	2	2	2	2
14	3	0	1	2	2	1	2	2	1	1	2	1	3	2	2	2	1	1	1	2	1	2	1	3	1	1	2
15	3	1	2	2	2	0	2	2	0	1	2	1	3	2	2	1	0	2	1	2	2	2	2	3	1	2	2
16	3	1	2	2	2	1	3	2	2	1	2	1	3	0	2	2	1	2	1	2	2	2	2	2	3	2	2
17	3	0	1	2	2	0	2	2	2	1	2	2	3	2	2	2	1	2	2	1	2	2	2	2	3	1	2
18	3	1	1	2	0	1	1	2	1	1	2	2	3	2	1	2	1	2	2	0	2	2	2	2	2	2	2
19	3	1	2	2	1	0	2	3	1	1	2	2	3	2	2	2	2	2	2	0	2	1	2	3	2	2	2
20	3	0	2	2	2	1	1	3	2	1	2	2	3	2	2	1	2	1	2	1	3	2	2	3	2	2	2
21	3	1	1	2	2	0	1	2	2	1	2	2	3	1	1	1	2	2	2	2	2	2	2	2	1	1	2
22	3	1	2	2	2	2	3	3	2	1	2	2	3	1	2	2	2	2	1	2	2	2	2	2	2	2	2
23	3	1	2	2	1	0	3	2	2	1	2	1	3	2	2	2	2	1	1	2	2	2	2	2	2	2	2
24	3	0	2	2	3	1	2	2	2	1	2	2	3	2	2	2	1	2	2	1	2	2	2	2	2	2	2

[illegible]