Livia

CLINICAL RESULTS

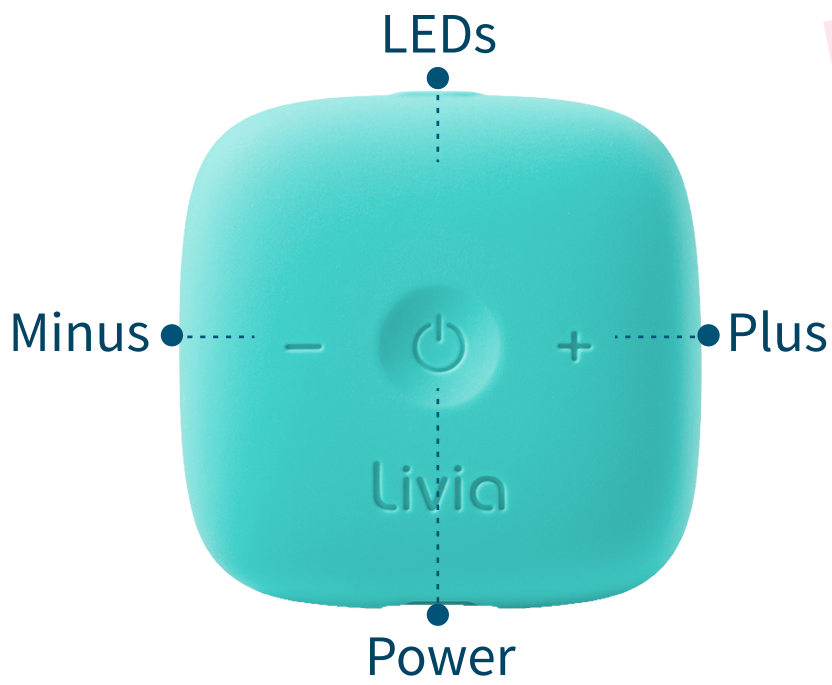
THE WORLD'S FIRST SCIENTIFICALLY PROVEN SOLUTION FOR PERIOD PAIN.

Menstrual cramps, or dysmenorrhea, are a common complaint among 80% of women of childbearing age. The pain can be so severe that it impacts daily functioning, leading to absences from school and work. Livia is a drug-free Class II medical device developed by iPulse Medical. In three clinical trials, Livia's patented SmartWave™ Pain Blocking Technology has been proven to deliver safe and effective relief of pain caused by menstruation. Targeted micro-pulses are transmitted via electrode pads that are placed on the lower abdomen or lower back. Utilizing Gate Control Theory, Livia's micro-pulses keep the central nervous system "occupied" and hence unable to receive menstrual pain signals. These micro-pulses also activate the body's natural pain control response by releasing beta endorphins to further suppress pain.

Since its inception in 2016, Livia has undergone extensive clinical trials under the supervision of renowned women's health expert, Dr. Bari Kaplan. The third study was conducted by TechnoSTAT, a leading data management and biostatistics company. All three clinical studies clearly documented that Livia delivers relief of menstrual pain effectively, quickly and safely. Livia is the only menstrual pain device on the market to receive FDA clearance. It also has CE and Health Canada approvals.

iPulse Medical is proud to provide women around the world with a convenient, effective, and drug-free solution for menstrual pain.

LIVIA DEVICE - SYSTEM SNAPSHOT



CLINICAL STUDY 01

INITIAL PROTOTYPE

CLINICAL ASSESSMENT OF PROTOTYPE DEVICE OVER 4 CYCLES

PARTICIPANTS

61 WOMEN

PROCEDURE

Conducted by:	Prof. Bari Kaplan
in the service of:	Beilison Hospital
Place	Tel Aviv

Participants were monitored during 4 cycles. During the first 2 cycles, no device was used. All women assessed their pain level and location. During the next 2 cycles, the Initial Prototype was used, with participants again assessing their pain level and location.

RESULTS

90% OF PARTICIPANTS reported pain reduction with Initial Prototype

59% OF PARTICIPANTS reported moderate relief

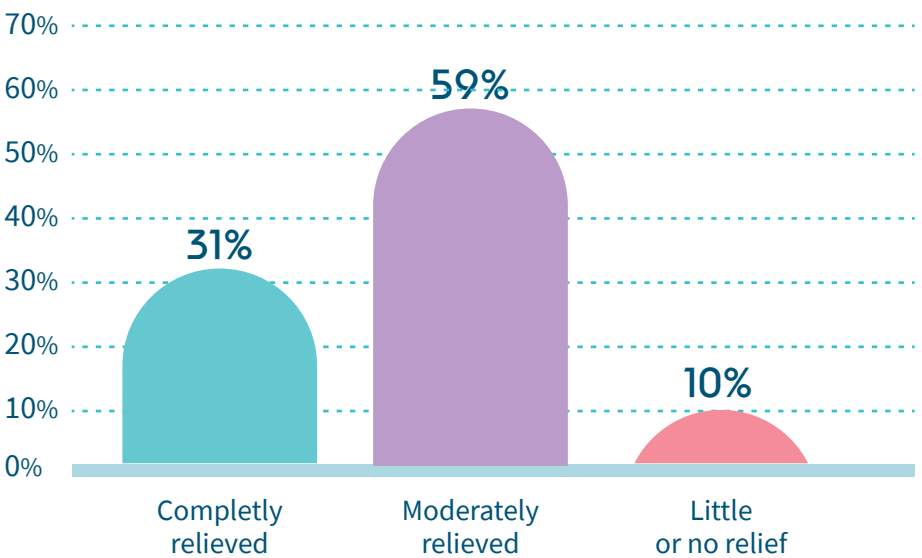
31% OF PARTICIPANTS reported complete pain relief

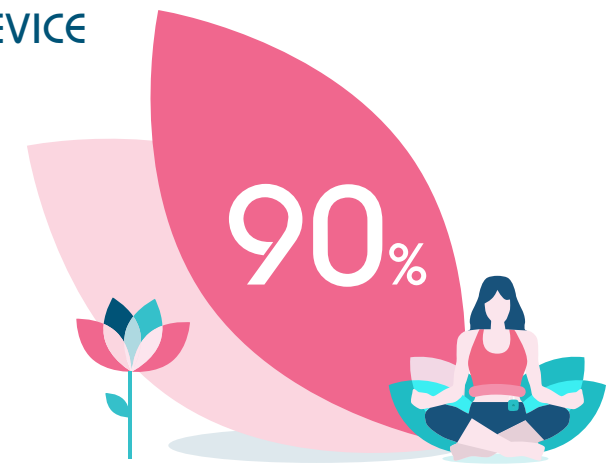
32% OF PARTICIPANTS observed that the Initial Prototype provided significantly faster pain relief than drugs

CONCLUSIONS

90% of study participants reported that the Initial Prototype provided effective relief from menstrual pain. Participants observed that Livia provided significantly faster pain relief than drug alternatives. No side effects were reported

% MENSTRUAL PAIN RELIEF AFTER USAGE OF LIVIA DEVICE





OF PARTICIPANTS REPORTED PAIN RELIEF

CLINICAL STUDY

02

IMPROVED PROTOTYPE

CLINICAL ASSESSMENT OF IMPROVED PROTOTYPE OVER 4 CYCLES

PARTICIPANTS

PROCEDURE

Conducted by:	Prof. Bari Kaplan
in the service of:	Beilison Hospital
Place	Tel Aviv

Participants were monitored during 4 cycles. During the first 2 cycles, no device was used. All women assessed their pain level and location. During the next 2 cycles, the Improved Prototype was used, with participants again assessing their pain level and location.

RESULTS

86% OF PARTICIPANTS reported pain relief

30% OF PARTICIPANTS reported moderate relief

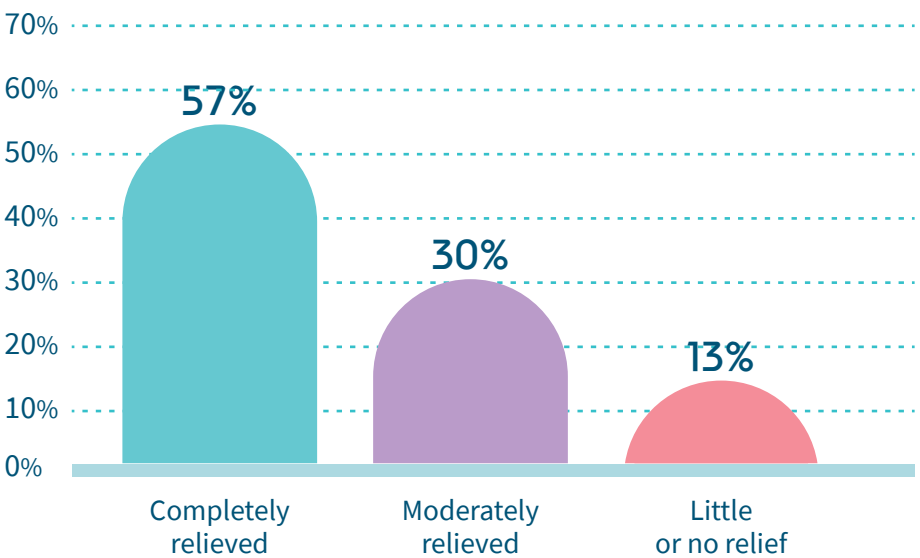
57% OF PARTICIPANTS reported complete pain relief

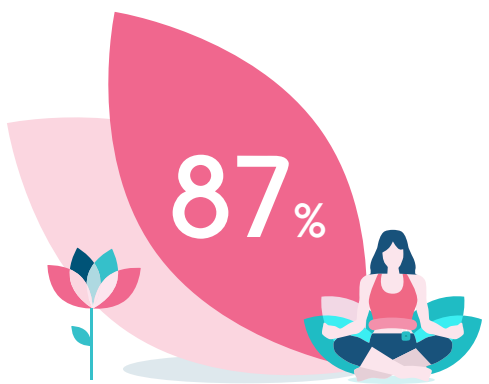
72.5% OF PARTICIPANTS reported that the device provided significantly faster pain relief than drugs

CONCLUSIONS

86% of study participants reported that the Improved Prototype provided effective relief from menstrual pain, with significant statistical improvements in efficacy and speed of action. 72.5% of participants observed that Livia provided significantly faster pain relief than drug alternatives. No side effects were reported.

% MENSTRUAL PAIN RELIFE AFTER USAGE OF IMPROVED DEVICE





OF PARTICIPANTS REPORTED PAIN RELIEF

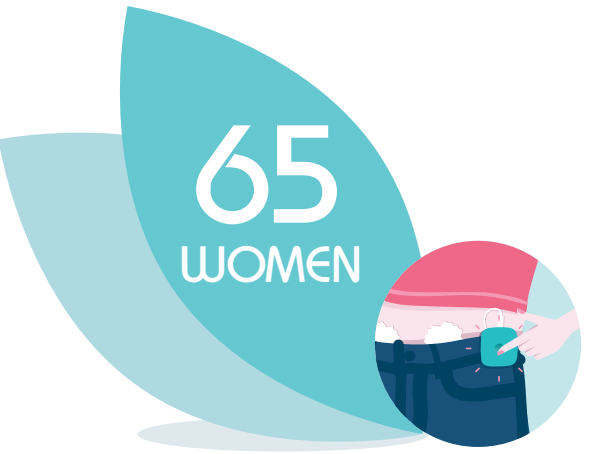
CLINICAL STUDY

03

FINAL PRODUCT

LIVIA VS SHAM DEVICE: DOUBLE-BLIND STUDY OF COMMERCIAL DEVICE OVER 2 CYCLES

PARTICIPANTS



PROCEDURE

Conducted by:	TechnoStat
in the service of:	4 geographically different study sites

Participants were randomly divided into Groups A and B and monitored during 2 cycles. Group A used Final Prototype during their first cycle and a Sham device during their second cycle; Group B used a Sham device during their first cycle and Final Prototype during their second cycle. Like the Final Prototype, the Sham device created a tingling sensation for the user when turned on. Each participant attended 3 supervised visits at study centers. During the first visit, participants were asked to evaluate their usual pain levels during their period as well as their quality of life; at the two subsequent visits, participants were asked to assess their pain level and quality of life and provide feedback on the device they were using.

STUDY TIMELINE

VISIT 1/BASELINE
Day 0

Within 10 days from last MP (pre-study)

Use of Livia/Sham during MP

VISIT 2
Day 30 (+/-10)

Up to 7 days from first study MP

Use of Livia/Sham during MP

VISIT 3 - END OF STUDY
Day 60 (+/-10)

Up to 7 days from second study MP

* The duration of subject participation in the study is up to 3 months

RESULTS

- The primary efficacy analysis of this study is based on VAS pain score. The use of Final Product succeeded in reducing the average difference in VAS score by 28.1 and 28.8 points (FAS and PP populations, respectively) compared to Sham which reduced the score only by 17.6 and 16.9 points (FAS and PP populations, respectively).
- A statistically significant difference was observed between the Final Product and the sham device (P <0.0001).
- Through qualitative questioning, participants observed a general improvement in their quality of life when using Livia.

CONCLUSIONS

Final Product significantly reduced participants' menstrual pain levels. Many women also reported an overall quality of life improvement as a result of Livia use. Multiple users noted Livia's ease of use and the sense of security it generates. No side effects or serious incidents were reported.

MIXED MODEL ESTIMATES OF VAS REDUCTION FOLLOWING THE DEVICE USE BY TREATMENT (FAS POPULATION)

Treatment	Mean VAS Reduction	Lower 95% CL	Upper 95% CL
Livia	-28.1	-32.3	-23.8
Sham	-17.6	-22.0	-13.3

Livia

The drug-free off switch
for menstrual pain. Period.

Contact Details:

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CLINICALLY PROVEN
APPROVED BY FDA
APPROVED BY CE
CH
EDISON AWARDS GOLD 2018 WINNER
THE ATLAS AWARD