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The Andalusian trial on heroin assisted  
treatment (HAT):  
a 2 years follow-up.

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# Context

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*Andalusia* (Spain), 8 million inhabitants

MT is dispensed mainly at **Primary Healthcare Centres**

*20,000 users* of MT registered in 2002.

4,700 (re)admissions for heroin/speedball/other opiates in 2004 –  
**(6,5% IV)**

Admitted to treatment for opioid addiction: 72% used heroin mixed with crack, chased (Junta de Andalucía, 2005).

*Granada* (Andalusia) 238,292 inhabitants

heroin/speedball/other opiates **20% IV (2002)**

*General profile of heroin users*: man, 35-44 years old, >8 years of education, low class, unemployed.

*General support to HAT* programs: **60 %** (PNSD, household survey 2005,).

# Framework

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Despite the availability and effectiveness of MMT, **many patients do not improve**, abandon the treatment, keep using illicit heroin while on MMT, remaining outside the coverage of public healthcare system

**Therapeutic alternatives** adapted to individual differences are needed.

Available clinical evidence indicates that **prescribed heroin for injection is effective**, feasible, safe and viable

**Further research in various contexts** was required, in order for these results to be generalised.

# The PEPSA trial

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RCT in Granada (Andalusia) between 2003 and 2004.

**Aim:** examining the efficacy of **injection DAM** compared to **oral Methadone** in a study sample of n=62 over a 9-month study period.

**Target group:** **regular opioid injectors** with at least two previous MMT episodes and **severe health or social problems**.

**Outcomes:** **significantly greater improvements** for drug-related risk behaviors, illicit heroin use, and health indicators in the experimental group.

**Both groups demonstrated significant intrinsic improvements** on key outcome indicators over time.

The **study showed that medically prescribed intravenous diacetylmorphine** is **safe, feasible and effective** in our context.

Trial participants (completers) continue to receive HAT, and those who received MMT were able to switch to HAT until fill out open slots, **under compassionate use principles**.

## 2 years follow-up: aim and methods

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**Aim:** to evaluate the health and drug use status among the participants in the Andalusian Heroin Assisted Treatment (HAT) trial, two years after the trial ended.

### Methods:

Data was collected between March and August 2006 by an independent team.

Validated questionnaires were used gathering information about socio-demographics profile, drug use and health.

Data analysis was performed for three groups in relation to their HAT history: **currently on HAT, discontinued HAT, never received HAT.**

## 2 years follow-up: recruitment

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Participants still receiving DAM were contacted at the **HAT clinic**.

The rest of them were located **using the contact information** from **field notes** of the recruitment team, visiting known **meeting-points**, and through **peers**.

Participants that were **incarcerated** were contacted through the collaboration of the Medical Director of the Granada Penitentiary Centre.

The study was approved by the Andalusian School of Public Health ethical and research board.

Participants signed an informed consent, and were economic compensated for their time.

## 2 years follow-up: Results

Fifty four participants, 87% from the total sample randomized in 2003, were interviewed.

Mean age was 39.02 (SD=5.26), and 87% of the participants were male.

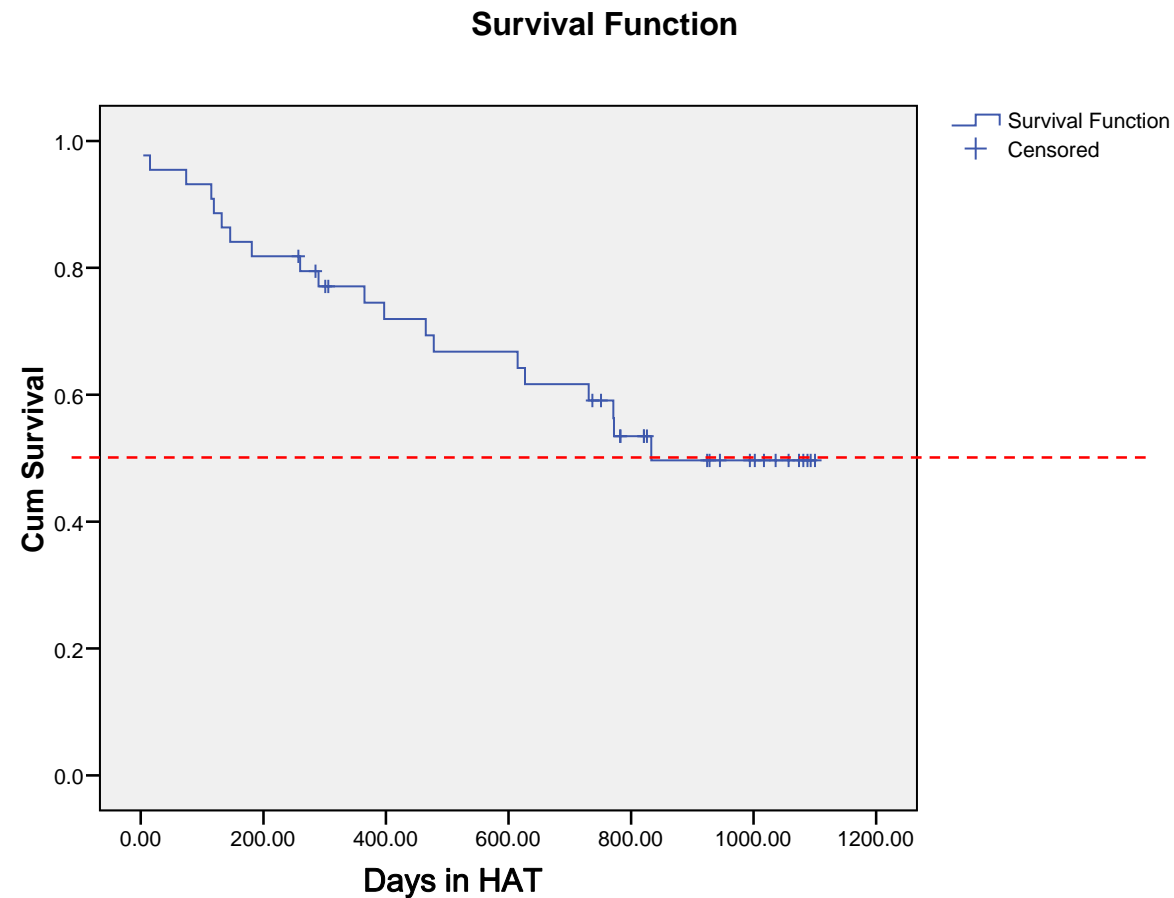
In relation to HAT treatment:

Never received HAT	22.2% (12)
Still in HAT	44.4% (24)
Discontinued HAT	33.3% (18)

No differences between these 3 groups were found among any of the baseline measures obtained before randomization.

## 2 years follow-up: retention in treatment

For those who at some point were on HAT, the mean days receiving DAM were 622.7 (Min=4; Max=1100; SD=359.24) and the retention rate at 3 years was 49.6%





## 2 years follow-up: Socio-demographics

No differences between the 3 groups were found among socio-demographic variables

Socio-demographic background	HAT currently	discontinued HAT	Never HAT	Total
Age (mean and SD)	39.5 (7.0)	38.4 (3.6)	38.9 (5.5)	39.0 (5.3)
Male	87.5%	83.3 %	91.7%	87%
Stable housing	87.5%	83.3 %	90.9%	86.8%
Welfare benefits	41.7%	50 %	50%	46.3%
Working in the last month (regularly or irregular)*	41.7%	25 %	20%	32.6%
More that half of the regular acquaintances do not use drugs	58.3%	38.9 %	33.3%	46.3%

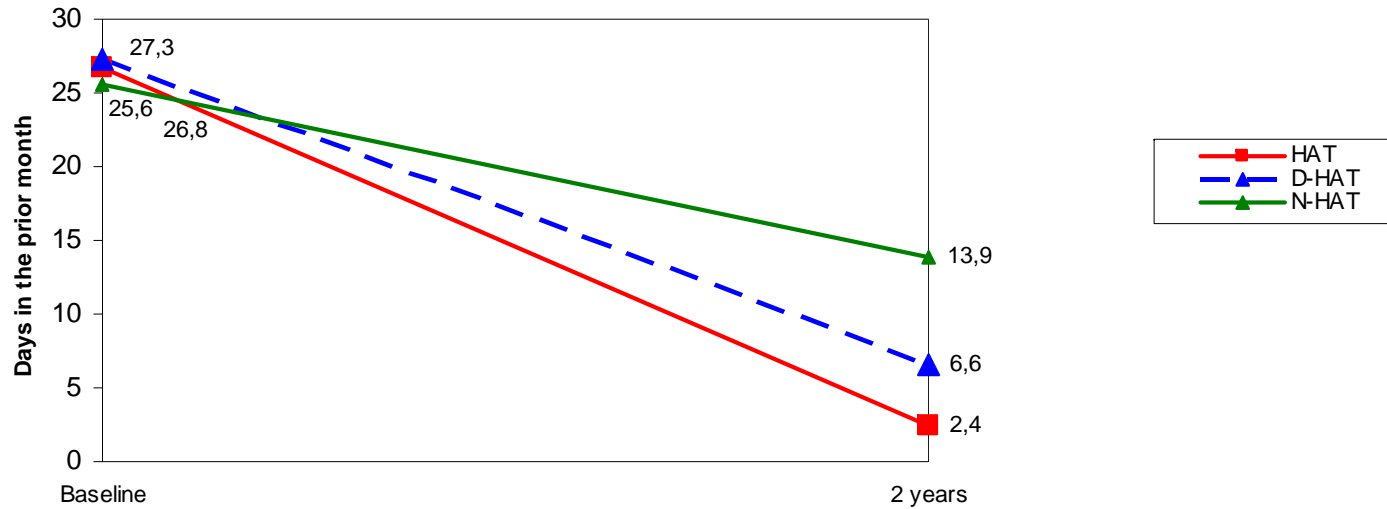
## 2 years follow-up: Health and drug scores

Variable	HAT currently		HAT in the past		Never HAT		p <sup>b</sup>
	Baseline	2 years	Baseline	2 years	Baseline	2 years	
Illegal activities <sup>d</sup>	11.58 (12.36)	0*	9.05 (12.14)	1.88 (5.30)	8.17 (12.45)	3.33 (10.00)	0.637
Illicit heroin (speedball) <sup>d</sup>	26.75 (7.13)	2.42 (3.02)*	27.25 (5.52)	6.56 (9.48)*	25.61 (9.31)	13.92 (12.59)*	<b>0.001</b>
Illicit benzodiazepines <sup>d</sup>	3.54 (7.29)	10.33 (9.50)*	7.10 (10.09)	20.33 (16.74)	7.56 (12.48)	10.60 (12.14)	0.555
OTI HIV risk	10.92 (3.66)	2.79 (7.10)*	12.45 (6.28)	7.22 (7.86)	10.83 (5.74)	9.58 (9.97)	<b>0.045</b>
MAP Health	23.54 (15.72)	19.96 (11.90)	22.85 (10.44)	27.94 (14.87)	23.78 (11.54)	29.58 (17.28)	<b>0.091</b>
SF12 Physical Health	40.53 (10.41)	44.55 (10.22)	43.98 (10.42)	38.40 (13.58)	44.27 (9.20)	45.82 (8.74)	0.152
SF12 Mental Health	30.49 (13.18)	40.08 (12.55)*	30.59 (12.20)	26.82 (11.75)	33.84 (13.36)	32.92 (10.9)	<b>0.004</b>
ASI Psychiatric Score	0.49 (0.18)	0.30 (0.19)*	0.52 (0.17)	0.49 (0.26)	0.46 (0.18)	0.41 (0.23)	<b>0.030</b>

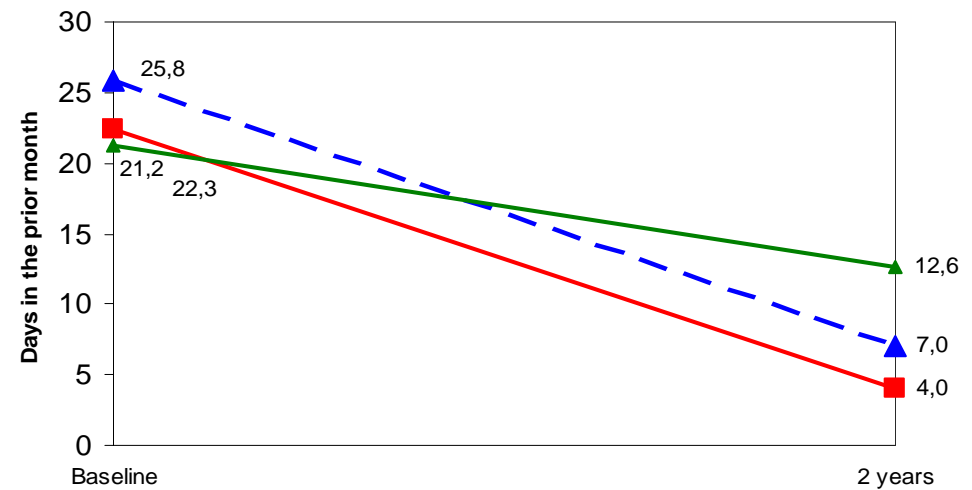
- a) Within groups comparisons Wilcoxon Ranks Test \*p<0.05  
b) Between groups comparisons for follow-up scores with Kruskal-Wallis Test  
c) Likert format 0 to 4; last 3 months, OTI scale.  
d) Number of days of use during the last month  
e) Speedball: this include one participant that use heroin alone

# 2 years follow-up:

## Illicit Heroin Use

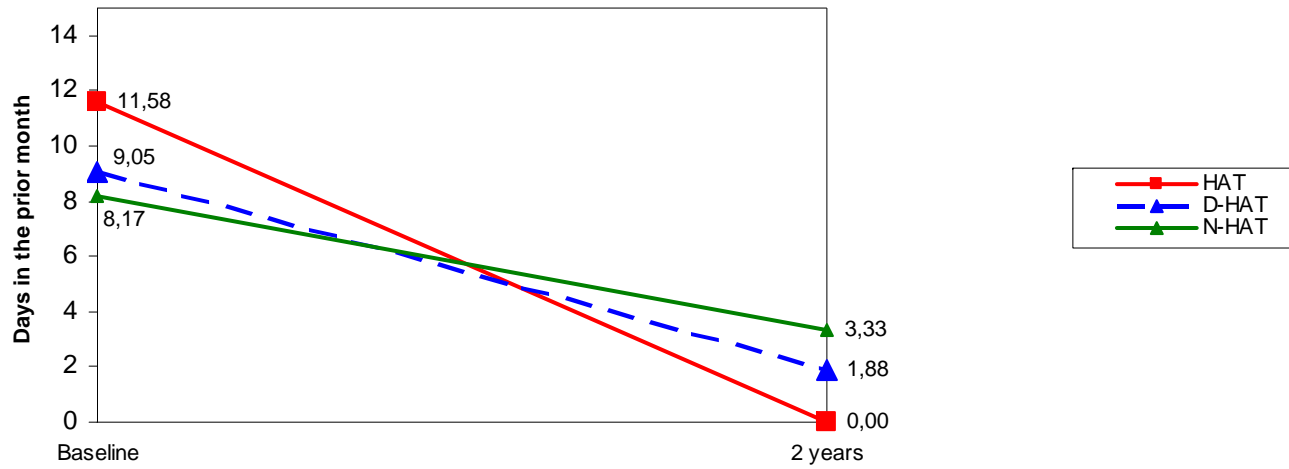


## Cocaine Use

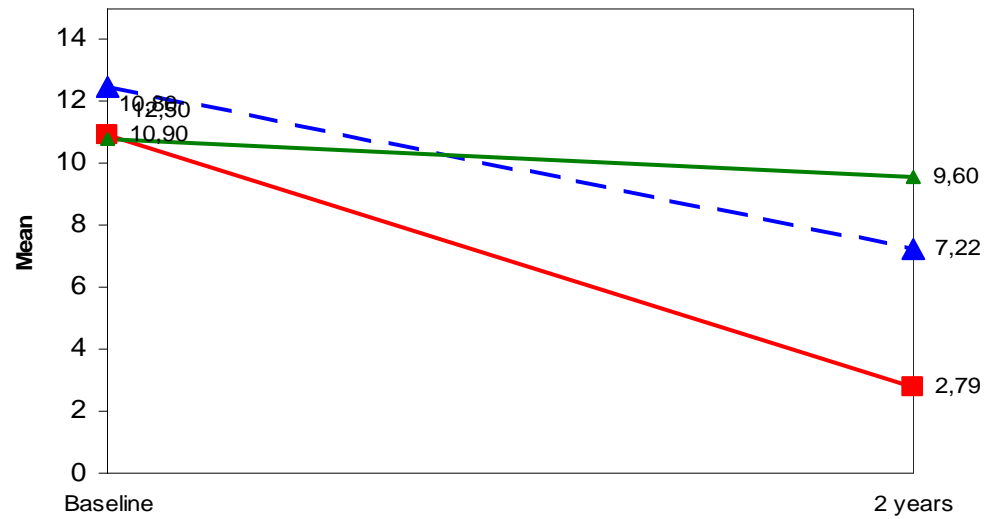


# 2 years follow-up:

### Illegal Activities

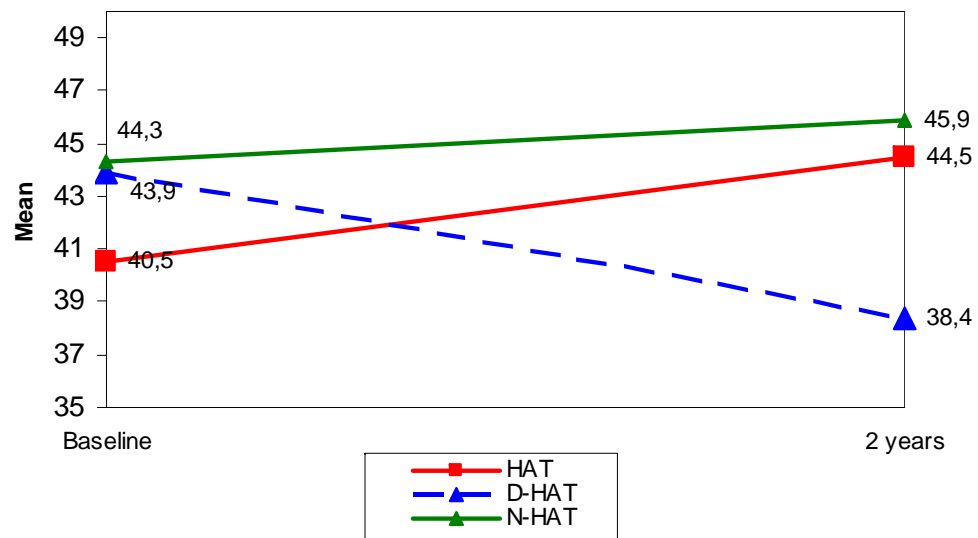


### OTI HIV Risk behaviour

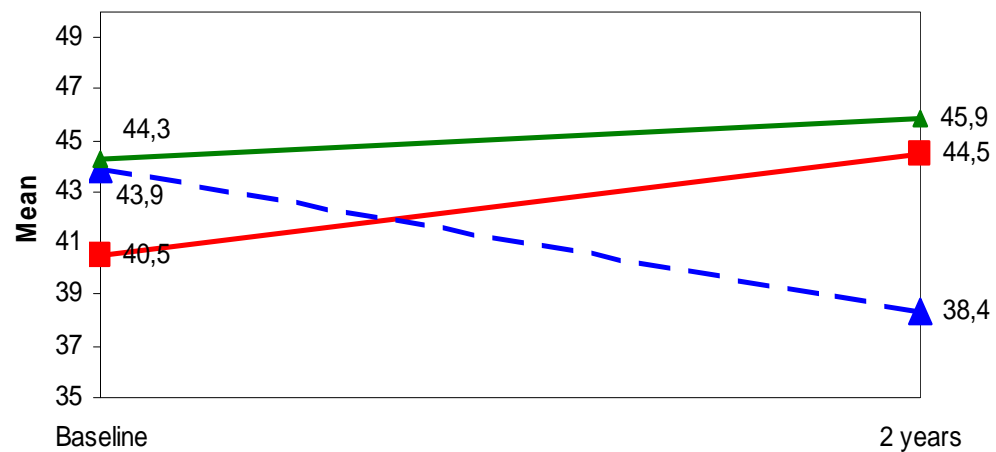


# 2 years follow-up:

## SF 12 Physical Health

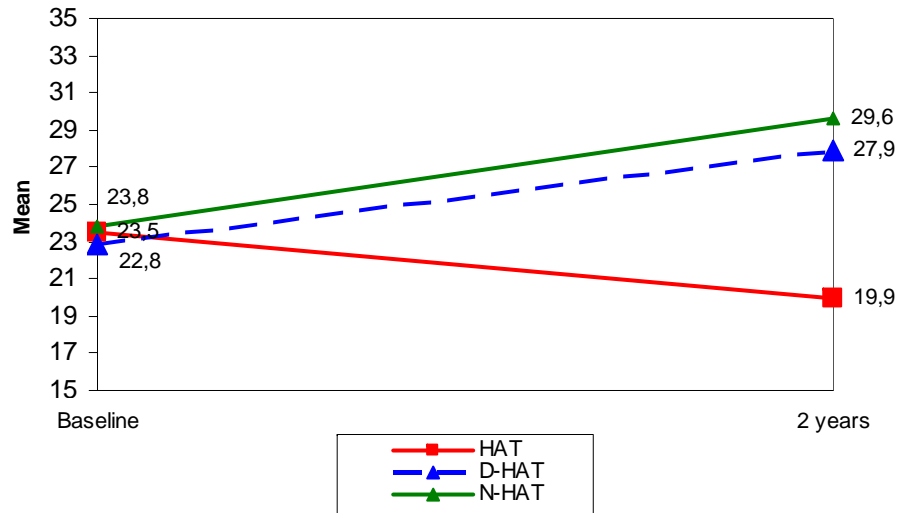


## SF 12 Mental Health

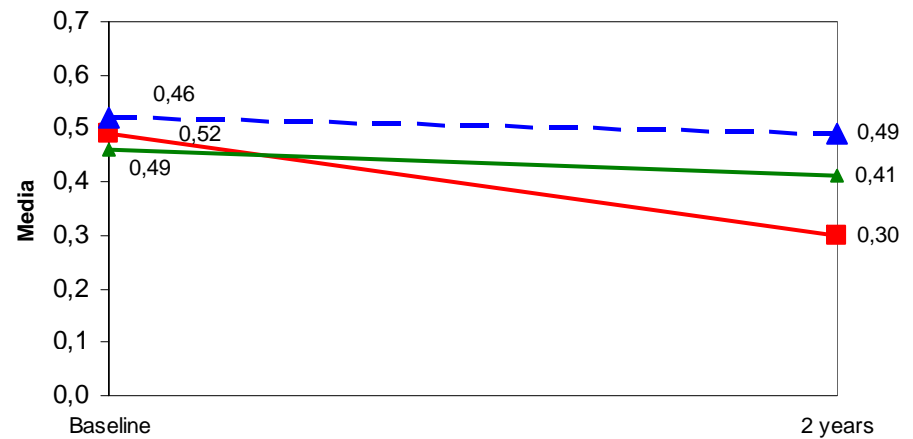


# 2 years follow-up:

### MAP Physical Health



### ASI Psychiatric Score



## 2 years follow-up: Discussion

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2 years after it finished....

Positive effect of the PEPSA trial: Those who were currently in HAT, had terminated or never received HAT showed a decrease in illegal activities, illicit heroin use, mental health and HIV risk behaviours.

Participants still receiving DAM had the most significant improvement (but at baseline equal or worst scores)

Those currently in HAT are the only group who showed improvement in physical health and HRQL.

## 2 years follow-up: final remarks...

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The main limitations derive from the **small sample size** that prevents further analysis of the main outcomes.

**Highly selected sub-sample** of opioid-dependent individuals: injectors, mainly male, heroin users for 20 years, socially excluded, with high levels of physical and mental health co-morbidities.

**After the trial period**, the HAT clinic management was organized as a regular substitution program, change that resulted in a **reduction of the staff**.

Many **participants left the HAT clinic** for reasons beyond non-compliance



## 2 years follow-up: recruitment

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The results of this study strength the **importance of HAT in the stabilization and improvement of physical and mental health** among a population of long term heroin users with severe co-morbidities and high mortality.

The **decline of heroin injectors** in Andalusia (and other parts of Europe) requires **urgent measures to make available other substitution options** besides methadone, such as oral heroin, to engage opioid-users in treatment.

Thanks!!!

